TGA THERAPEUTIC GOODS ADMINISTRATION

PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241
ABN 40 939 406 804

Commonwealth Department of Health and Ageing

Therapeutic Goods Committee
21st Meeting (11 February 2003)

Information for Stakeholders – Report on Meeting

The 21st Meeting of the Therapeutic Goods Committee (TGC) was held in Conference Room 1, Ground Floor, TGA Building, Narrabundah Lane, Symonston on 11 February 2003, commencing at 11.00 a.m. and closing at 4.35 p.m.

Present

TGC Members: Professor Stella O'Donnell (Chair)
Dr John Ballard
Dr Mark Bowden
Mr David Clayton
Ms Amanda Cornwall
Mr Philip Daffy
Mr Barry Evers-Buckland
Associate Professor Loraine Holley
Associate Professor William Rawlinson
Professor Klaus Schindhelm

TGA officers: Mr Paul Archer
Dr David Briggs
Ms Julie Emery
Mr Philip K. Harrison
Dr Larry Kelly
Ms Rita Maclachlan
Dr John McEwen
Dr Yook-Tau Pang
Dr Brian Priestly
Dr Glenn Smith
Mr Robert Tribe
Dr Raymond Wilson

Secretariat: Ms Lyn Lewis
Ms Linda McDonell

Apologies: Nil

AGENDA AND COMMITTEE ADMINISTRATION

Opening of Meeting – Welcome and Apologies

The Meeting was opened at 11.00 am. Members were welcomed to the first Meeting since the Committee had been re-appointed and were invited to briefly outline their background and expertise. It was noted that there currently was no Member representing Standards Australia.

Members were advised that a number of TGA officers would be attending the Meeting for the discussion of agenda items of relevance.

Members had participated in a series of information sessions prior to commencement of the Meeting and these were noted to have been of particular value to those Members joining the Committee for the first time.

Terms of Reference

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*. Attention was drawn to the additional functions of the Committee now included in Regulation 34 as a result of the introduction of the new medical devices legislation.

Adoption of Agenda

Members noted the agenda as presented and agreed to a proposal to defer consideration of the establishment and Terms of Reference of TGC Subcommittees until completion of the other agenda items which would have a bearing on this.

Confidentiality provisions applying to Committee papers were noted.

Conflict of Interest Declarations

In accordance with the Guidelines on Confidentiality and Conflict of Interest adopted by the Committee at its November 2000 Meeting, 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. In this event, 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 20th Meeting of TGC

Members noted that the Minutes of the 20th Meeting of the TGC were ratified out-of-session on 5 June 2002 according to the process previously determined by the Committee, and that the key resolutions and a subsequent report on the Meeting had been published on the TGA website.

MEDICINAL PRODUCTS

Adoption of British Pharmacopoeia 2002

The TGC considered the need to amend the definition of British Pharmacopoeia (BP) included in the *Therapeutic Goods Act 1989* (the Act) to update the edition of that publication adopted in Australia as the principle standard for medicines and other therapeutic goods. Since 1 December 2001, the edition effective in Australia had been BP 2001, however BP 2002 had since been published.

The Committee noted the extent and nature of changes that had occurred to BP monographs since the publication of the previous edition, and also that a considerable number of amendments had occurred to monographs of the European Pharmacopoeia which flowed through to the BP.

Consultation with peak industry associations (Medicines Australia, ASMI, CHC, MIAA, GMIA, CTFAA, ACSPA and ADIA) had been undertaken and, generally, there was no objection to adoption of BP 2002. Overall, few issues had been raised – these related to:

- The addition to the BP of monographs for homoeopathic preparations and the increasing number of monographs for herbals and herbal extracts; and
- The policy of the BP remaining the principal reference standard in Australia.

With regard to homoeopathic preparations, the TGC noted the intention of the Office of Complementary Medicines (OCM) to undertake a full review of the regulation of homeopathic preparations and that, in the interim, the OCM was willing to consider requests for exemption from BP requirements on a case-by-case basis.

With regard to the BP remaining the principle reference standard in the Act, two specific issues were raised by industry representatives. These were the continued role and status of the BP as the default standard, and the time given to sponsors to implement changes arising from the adoption of new editions. The TGC was advised of a divergence of views among industry in relation to the former issue. In relation to the latter issue, annual publication meant only a short lead-time for sponsors to consider the implications of amendments and implement changes to documentation and products.

The TGC agreed that no technical issues had been identified that precluded adoption of BP 2002 and that an appropriate date for adoption would be 1 April 2003. However, the TGA was requested to explore, and report back on, mechanisms to allow sponsors a defined transition period for implementation of changes into documentation subject to GMP inspection.

In relation to the continuation of the BP as the principal standard, the TGC viewed this as a policy issue for consideration within the context of the possible joint Trans-Tasman agency.

RESOLUTION NO. 21/01

> **The Therapeutic Goods Committee recommends the adoption of the British Pharmacopoeia 2002 on 1 April 2003 for the purposes of the edition of the British Pharmacopoeia defined under the *Therapeutic Goods Act 1989*.**

Consequential consideration of Amendment to TGO 70 *Standards for Export Only Medicine*

Amendment of Therapeutic Goods Order No. 70 *Standards for Export Only Medicine* (TGO 70) to replace reference to BP 2001 with BP 2002 was a consequential consideration. It was noted that, in recommending adoption of TGO 70 at its Meeting in November 2001, the TGC had advised that TGO 70 should be maintained to reflect the most recent editions of each of the referenced pharmacopoeias.

The TGC now supported this amendment to TGO 70, also with an effective date of 1 April 2003, as this action was necessary to ensure consistency in standards.

RESOLUTION NO. 21/02

> **The Therapeutic Goods Committee recommends that Therapeutic Goods Order No. 70 *Standards for Export Only Medicine* be amended to replace the reference to British Pharmacopoeia 2001 with reference to British Pharmacopoeia 2002 with effect 1 April 2003.**

Child Resistant Packaging – Finalisation of New Therapeutic Goods Order

The TGC noted the background to the review of requirements for child-resistant packaging (CRP) and considered stakeholder responses arising from the consultation undertaken on the revised draft of Therapeutic Goods Order No. 65 *Child-resistant packaging for therapeutic goods* (TGO 65) in September/October 2002.

Several industry associations and other stakeholders had provided comments and, as a consequence, the TGC agreed to a number of minor amendments. These included:

- Subclause 1(1)(a)(iv) – expand to except semi-solids such as eye gels from the requirements of the Order;
- Subclause 2(1) – amend definition of 'blister' so that it does not exclude products where individual blisters hold more than one tablet or capsule that are intended to be extracted together and taken as a single dose;
- Clarification in the Supplementary Notes of the intent of subclause 4(5)(a) concerning the range of containers on which the sponsor is required to hold information;
- Deletion of proposed requirement for all components of reclosable containers to be identifiable through manufacturer's markings;
- Clarification of Supplementary Notes to more clearly differentiate notes relating to reclosable and non-reclosable packages; and
- Correction to details included in the Second Schedule on packaging components.

Noted in relation to the First Schedule of the draft TGO were:

- Comments from an industry association regarding the significant increase in number of products that will require CRP and from another stakeholder relating to the rationale for inclusion of some substances in the First Schedule;
- Aspects of the *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally Review) relating to the risks and benefits of packaging controls, including CRP, and the divergence of submissions to that Review on this issue;

- The need for CRP requirements to be based on a balance between risks and benefits;
- That inclusion of class groups was intended to ensure similar controls applied to substances expected to present similar hazards, and to obviate the need for amendment to the Order with each new chemical entity approved;
- The ability, under section 14 of the Act, for sponsors to seek an exemption from the requirements of the Order if this could be justified; and
- That no amendment to the First Schedule was warranted at this time, although a number of issues could be referred to CRP Subcommittee for future consideration.

In relation to standards for non-reclosable packaging included in the draft TGO, the TGC noted that these were the same as currently in force. Developments overseas to implement standards for non-reclosable forms of CRP were noted and it was agreed that this issue also would need to be considered by the Subcommittee in the future. The views of one stakeholder concerning the inadequacy of blister packaging for paracetamol products were noted.

Having considered stakeholder responses and agreed to the amendments as described above, the TGC resolved:

RESOLUTION NO. 21/03

The Therapeutic Goods Committee:

- **Endorses the amended draft Therapeutic Goods Order No. 65 *Child-resistant packaging for therapeutic goods*; and**
- **Recommends the gazettal of this Therapeutic Goods Order as a standard for therapeutic goods made under section 10 of the *Therapeutic Goods Act 1989.***

Review of Limits for Content of Minerals in Tablets and Capsules Specified in Therapeutic Goods Order No. 56

Potential conflicts of interest were declared by Dr Bowden and Mr Clayton on the basis of their employment. Following consideration of this in terms of the TGC's Conflict of Interest Guidelines and the role of these Members in representing the interests of the prescription and non-prescription medicines sectors, the Committee agreed that Dr Bowden and Mr Clayton should be permitted to participate in the discussion, but not vote on the matter.

The TGC considered a submission from the Australian Self-Medication Industry Inc. (ASMI) seeking revision of the First Schedule of Therapeutic Goods Order No. 56 *General standard for tablets, pills and capsules* (TGO 56) to allow widened limits for content for a range of minerals when present in multi-mineral, or multi-mineral and vitamin, tablets or capsules.

The widened limits sought were 90-125 per cent for calcium, copper, iron, magnesium, manganese, phosphorus, potassium, zinc and sodium, and 90-200 per cent for chromium, fluorine, iodine, molybdenum and selenium. Currently the limits applying to these minerals were 92.5-107.5 per cent of the stated content.

The TGC noted that the proposal was based largely on the arguments that:

- The widened limits would more closely align with the limits permitted in the relevant USP monographs;

- Meeting current requirements can be difficult for manufacturers and result in costly and unnecessary rejection of batches;
- Precedent, in that TGO 56 allowed widened limits for vitamins contained in multivitamin preparations that were closely aligned with those of the USP; and
- The absence of significant safety issues.

In considering the submission, the TGC also took into account advice that:
- With the proposed increase for chromium, fluorine, molybdenum and selenium to 200 per cent, there was potential to change exposure to these trace elements quite significantly. Whether this would impact on safety depended on the tolerable upper intakes for these elements and total exposure, not only from supplements but also diet and water. The amounts obtained from these other sources in Australia were not known;
- As some of the minerals to which the submission related were scheduled poisons, the National Drugs and Poisons Schedule Committee (NDPSC) should be afforded the opportunity to comment, as poisons scheduling cut-offs were based on the upper content limit being no more than 107.5 per cent of the stated content;
- Any consequential decision by the NDPSC to reduce the level at which poisons scheduling takes effect may impact on formulations. ASMI's alternative proposal, to allow the increased content limits only for products containing up to 50 per cent of the amount at which poisons scheduling takes effect, may obviate this problem although consistency with the USP would not be achieved;
- Any widened limits should only apply to multi-mineral products and not products containing a single mineral; and
- The case for sodium was not convincing and this mineral was not included in the USP monographs.

The TGC noted that a number of other aspects of TGO 56 required review, and that more extensive amendment to the Order would probably be necessary following this review.

Following consideration of the associated issues, the TGC gave in-principle support for harmonisation with the limits applied by the USP for the minerals calcium, copper, iron, magnesium, manganese, phosphorus, potassium, zinc, chromium, fluorine, iodine, molybdenum and selenium when these are present in multi-mineral, or multi-mineral and vitamin, products. However, until safety issues were fully considered, the TGC recommended that the USP limits should not be applied to products formulated to contain any more than 50 per cent of the nominal amount at which poisons scheduling takes effect.

This in-principle support for widened limits was given in the context of the pending review of TGO 56 during which safety considerations relating to the increased limits could be considered more fully. The recommendation would provide an interim solution for industry and guidance for the TGA in considering applications for exemption.
The TGC therefore resolved:

RESOLUTION NO. 21/04

> **The Therapeutic Goods Committee recommends the following approach be taken by the TGA when considering requests for exemption from the requirements of Therapeutic Goods Order No. 56 *General standard for tablets, pills and capsules* relating to content limits for minerals contained in**

multi-mineral and multi-mineral/multivitamin products:

- **The permissible limits should be those of the current *United States Pharmacopeia* (USP) except for those elements which are subject to a Schedule in the *Standard for the Uniform Scheduling of Drugs and Poisons;***
- **For those elements subject to a Schedule in the *Standard for the Uniform Scheduling of Drugs and Poisons:***
  - **The USP limits should only apply to those products stated to contain no more than 50 per cent of the scheduled amount;**
  - **In all other cases, the limits that apply should be no less than 90 per cent and no more than 125 per cent of the stated content.**

In order to review TGO 56 fully, the TGC recommended the establishment of a Subcommittee with appropriate expertise and representation. The composition and Terms of Reference of this Subcommittee would be considered at the TGC's next Meeting. To facilitate the review however, the TGA was requested to invite stakeholders to identify any particular concerns held with TGO 56. The TGC therefore resolved:

RESOLUTION NO. 21/05

The Therapeutic Goods Committee recommends that:

- **At its next Meeting, a Subcommittee be established to review Therapeutic Goods Order No. 56 *General standard for tablets, pills and capsules* (TGO 56) and associated matters; and**
- **Before that Meeting, the TGA should canvass stakeholders in order to identify issues for consideration in the review of TGO 56.**

Medicine Labelling – TGA Labelling Review and Performance Based Labelling

At its 20th Meeting in April 2002, the TGC had given in-principle support to the consolidation of all required warning statements for medicines in Therapeutic Goods Order No. 69 *General requirements for labels for medicines* (TGO 69).

The TGC was now advised that the TGA Label Reference Group had determined that this action was more complex than anticipated, and that inclusion of warning statements in a schedule or appendix to TGO 69 would not allow for the frequency of amendments likely to be needed. It was therefore proposed to develop a separate document, *Required Advisory Statements for Therapeutic Goods*, that would be referenced in the Therapeutic Goods Regulations (the Regulations) and linked to TGO 69. Referencing in the Regulations would allow this document to be updated from time to time as necessary, without amendment to TGO 69. The new document would come into effect in July 2004.
The necessary changes to TGO 69 would be relatively simple, involving only a change to the definition of 'warning statements' included in clause 2 'Interpretation', with deletion of reference to the Poisons Standard (i.e. the SUSDP) and insertion in its place of reference to the new document. Action to amend TGO 69 would need to be taken in late 2003.

The TGC noted that, following consolidation of the SUSDP warning statements into this new document, the TGA proposed to transfer other label warning statements currently contained in various regulatory documents.

The TGC were also informed of the development of an industry Code of Practice for performance-based labelling of non-prescription medicines, which would be co-regulated by the TGA and industry. The TGC were requested to consider referencing this Code in TGO 69, through the addition of a statement on the principles of labelling of non-prescription medicines to the introduction to TGO 69, and a specific reference to the Code in the Supplementary Notes section. This would advise that compliance with the statement on the principles of labelling of non-prescription medicines could be achieved through following the guidelines given in the Code of Practice.

Following discussion, the TGC resolved that:

RESOLUTION NO. 21/06

The Therapeutic Goods Committee gives in-principle support to:

- **The linking of Therapeutic Goods Order No. 69 *General requirements for labels for medicines* to the TGA's proposed document *Required Advisory Statements for Therapeutic Goods*; and**
- **The proposal to add a statement on the principles of labelling of non-prescription medicines to Therapeutic Goods Order No. 69 *General requirements for labels for medicines* with a reference to the Industry Code of Practice *Designing medicine labels for people* to be included in the Supplementary Notes to the Order.**

BLOOD AND TISSUES

Standards for Haemopoietic Stem Cell (HSC) Products

At its 20th Meeting, the TGC had recommended amendment of Therapeutic Goods Order No. 66 *Standards for Blood Components* (TGO 66) to adopt the 8th Edition of the Council of Europe (CoE) document *Guide to the Preparation, Use and Quality Assurance of Blood Components* (the Guide) as the standard applicable to these goods. As TGO 66 defined haemopoietic stem cells (HSCs) as blood components, the standard for these goods was that given in the 8th edition of the CoE Guide.

The TGC was informed that the 9th edition of the CoE Guide, due for consideration by the Committee at its next Meeting, excised the chapter on HSCs and incorporated this in a separate CoE Guide for Cellular Products. Therefore unless Australia adopted a specific standard for HSCs, there would be a deficiency in the regulatory system for these products once the 9th edition of the Guide was adopted under TGO 66.

To consider options available for a new standard for HSCs in Australia, the TGA had convened an *ad hoc* expert Advisory Group to examine relevant overseas and Australian standards and consider which would be most appropriate for adoption in Australia. The Group considered but rejected developing a unique Australian Standard because of the international nature of the sector in terms of donor registries and the need to allow import and export of products.

A number of contentious issues emanating from each standard were identified but, following rigorous analysis and consultation within the sector, the Advisory Group had recommended adoption of:

- The Second Edition of the Netcord / Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) *International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release* through a Therapeutic Goods Order for Haemopoeitic Stem Cells harvested from placental cord blood; and

- The Second Edition of the Foundation for the Accreditation of Cellular Therapy (FACT) *Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation* through the Therapeutic Goods Order for Haemopoeitic Stem Cells harvested from sources other than placental cord blood, subject to the inclusion of a preamble to clearly identify the scope of TGA regulation of HSC products and to differentiate this from medical practice issues, as well as identifying related documents that may take precedence.

The TGC agreed that adoption of specific standards for HSCs was important as this field was progressing rapidly, and noted advice that the TGA would negotiate with FACT / FAHCT regarding the adoption of the above standards. Also, because current provisions in the Therapeutic Goods Regulations exempted autologous and directed products from regulation, the TGA would initiate wider consultation to assess the impact of extending its oversight to this sector.

The TGC noted a number of comments on the technical content of the two documents that required further consideration, and agreed that practical issues associated with implementation in Australia of the nominated standards could be progressed through an *ad hoc* Working Party, based on the membership of the Advisory Group. The next Meeting of the TGC should then be able to make a recommendation on the adoption of the nominated standards through TGOs.

RESOLUTION NO. 21/07

The Therapeutic Goods Committee establishes an *ad hoc* Working Party to be chaired by Associate Professor William Rawlinson to:

- **Consider the adoption of the 2nd edition of *International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release* [NETCORD and Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) (July 2001)] as the basis of a Therapeutic Goods Order for Haemopoietic Stem Cells Harvested from Placental Cord Blood;**

- **Consider the adoption of the 2nd edition of *Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation* [Foundation for the Accreditation of Cellular Therapy (FACT) (2002)] as the basis of a Therapeutic Goods Order for Haemopoetic Stem Cells Harvested from Sources Other than Placental Cord Blood; and**
- **Provide a report for consideration at the next Meeting of the Therapeutic Goods Committee.**

MEDICAL DEVICES

New Medical Devices Legislation

The TGC noted that the new regulatory system for medical devices had been implemented on 4 October 2002. While a system of non-mandatory medical device standards and conformity assessment standards replaced mandatory Therapeutic Goods Orders (TGOs) that currently existed for medical devices, all existing TGOs would need to be retained for at least five years to cover products that were registered or listed prior to transition.

Lists of medical device standards and conformity assessment standards developed by the TGA as part of the new regulatory system for medical devices were noted. These lists included standards that:

- Had been included into a draft order for gazetting;
- Had been recommended by the relevant Standards Australia International Committee for adoption but needed some further consideration in regard to their relationship with the Essential Principles; or
- Were not proposed for adoption at the present time.

The TGA had conducted a review of existing TGOs relevant to therapeutic devices under the new legislation. The following advice was noted:

- Where the purpose of a TGO was to mandate an international or Australian standard, such as TGO 28, S*tandard for Contraceptive Devices - Diaphragms*, it was proposed that the standard be included in a new Order as a medical device standard, and the TGO eventually be revoked;
- Where a TGO invoked an international or Australian standard, but included modifications for regulatory purposes, such as TGO 59 *Polymer Catheters for General Medical Use* and TGO 41 *Single Use Syringes (Sterile) for injection of 100 Units per Millilitre (U 100 Insulin)*, it was proposed that the standard be included in a new Order as a medical device standard. The modifications, if still relevant, would be included as "other matters" specified in the new Order.
- TGO 53, S*tandard for Single-use (Sterile) Rubber Surgical Gloves* referenced standard AS/NZS 4179:1997 which was significantly different from the European harmonised standards EN 455-1 and EN 455-2. This matter had been referred to the relevant Standards Australia committee and the recommendation had been that the Australian standard be retained.
- TGO 54, for all disinfectants, had no international or Australian standard equivalent. This had been discussed by the Disinfectant Working Party, which had agreed that a revised and reformatted version of TGO 54 should be included in a new order as a medical device standard. The revised version of the TGO would be referred to TGC when finalised.
- TGO 49 G*eneral Standard for Sutures* had been considered by the Therapeutic Devices Evaluation Committee to be out of date, and that committee had supported consideration of the suture-specific EP/BP monographs for suitability as suture standards in Australia.

RESOLUTION NO. 21/08

The Therapeutic Goods Committee notes:

- **The process for adoption of Medical Device Standards under the new**

legislation implemented in October 2002;

- **The Medical Device Standards proposed for gazettal[1];**
- **The list of standards not recommended for adoption at the present time[2]; and**
- **The list of standards which need further consideration[3].**

Therapeutic Goods Orders Relating to Therapeutic Devices

The TGC noted the gazettal of Therapeutic Goods Order No. 67A *Amendment to TGO 67: Standard for Dental Materials* on 14 August 2002. This Order adopted the new ISO Standard 4049:2000 *Dentistry – Polymer-based filling, restoration and luting materials* which superseded ISO 4049:1988 *Dentistry – Resin-based filling material* and would come into effect 12 months from the day it was gazetted in the Commonwealth of Australia Gazette.

RESOLUTION NO. 21/09

The Therapeutic Goods Committee notes the gazettal of Therapeutic Goods Order No 67A *Amendment to Therapeutic Goods Order No. 67 – Standard for Dental Materials.*

OTHER MATTERS

Review of the Code of Good Wholesaling Practice for Therapeutic Goods for Human Use

Review of the Australian *Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*, which had been published in 1991, had been referred by the National Coordinating Committee on Therapeutic Goods (NCCTG). Historically the document had been maintained and published by the TGA although it was taken up under State and Territory legislation relating to the licensing of wholesalers rather than the *Therapeutic Goods Act 1989*.

In considering the need for this review, Members noted the following:

- Standards for distribution were related to ensuring the quality of medicines and medical devices when they reach the end-user;
- There was a need for the Code to be aligned with GMP principles and requirements;
- The term 'good wholesaling practice' may no longer be appropriate as distribution functions could be undertaken by companies or organisations that were not required to be licensed as wholesalers under State law. The term 'good distribution practice', as used in Europe, encompassed a wider range of distribution practices and was more relevant to the medical devices industry; and
- Consideration needed to be given to inclusion of a requirement for batch distribution records for reference in case of recalls.

1 See Attachment 1
2 See Attachment 2
3 See Attachment 3

The TGC agreed that the review would best be undertaken by an *ad hoc* Working Party established specifically for this purpose, with membership including representatives of:

- State health authorities responsible for licensing wholesalers (NSW and Victoria);
- The National Pharmaceutical Services Association;
- Distributors of therapeutic goods;
- Industry, with appropriate expertise, including medical devices; and
- The TGA.

The Working Party would be chaired by Professor O'Donnell. The TGC therefore resolved:

RESOLUTION NO. 21/10

- **The Therapeutic Goods Committee establishes an *ad hoc* Working Party to be chaired by Professor Stella O'Donnell in order to further develop a revised code for the distribution of therapeutic goods and report to the next Meeting of the Committee.**
- **The Working Party is to have appropriate representation from relevant stakeholders.**

CLOSE OF MEETING

The TGC agreed that, in view of the number of issues soon requiring consideration, two further meetings should be held this year. These would be in June and October/November. A date for the next Meeting would be determined out-of-session.

The Chair thanked Members of the Committee for their participation and closed the Meeting at 4.35 pm.

The Minutes of the 21st Meeting of the TGC were ratified by Members out-of-session and signed by the Chair on 21 April 2003 as a true and correct record of the Meeting.