Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Committee

29TH MEETING (7 SEPTEMBER 2006)

INFORMATION FOR STAKEHOLDERS – REPORT ON MEETING

The 29th Meeting of the Therapeutic Goods Committee (TGC) was held in Conference Room 1, TGA Building, Narrabundah Lane, Symonston ACT on 7 September 2006, commencing at 10:05am and closing at 4:00pm.

Present

TGC Members:	Professor Stella O'Donnell (Chair) Dr Mark Bowden Mr David Clayton Mr Philip Daffy Mr Barry Evers-Buckland Associate Professor Loraine Holley Mr John Stubbs
Apologies:	Dr John Ballard Associate Professor William Rawlinson Professor Klaus Schindhelm
TGA officers:	Dr Vivienne Christ (part meeting) Dr Jorge Garcia (part meeting) Mr Philip K Harrison (part meeting) Dr Larry Kelly Ms Linda Punyer (part meeting) Dr Bill Sherwin (part meeting)
Secretariat:	Ms Margaret Joy Ms Lyn Lewis (Secretary)

AGENDA AND COMMITTEE ADMINISTRATION

OPENING OF MEETING – WELCOME AND APOLOGIES

The Chair opened to Meeting at 10:05am 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 a slight variation in the order of discussion.

CONFLICT OF INTEREST DECLARATIONS

Members submitted their completed Disclosure of Interest Declarations in accordance with Committee procedures. No conflicts of interest relevant to the Meeting were declared.

MINUTES OF THE 28TH MEETING OF THE TGC

The TGC noted that the Resolutions and Minutes from its 28th Meeting held on 24 January 2006 had been ratified out-of-session in accordance with usual procedures. Key Resolutions from that Meeting and a report for stakeholders were subsequently posted on the TGA website. The TGC therefore resolved:

RESOLUTION:

The Therapeutic Goods Committee NOTES that:

- **the Minutes of the 28th Meeting of the Therapeutic Goods Committee held on 24 January 2006, were ratified out-of-session as a true and accurate record of that Meeting; and**

- **the documents *Summary of Key Resolutions* and *Information for Stakeholders – Report on Meeting* have been published on the TGA website.**

ACTIONS ARISING FROM THE 28TH MEETING OF THE TGC

Members noted the report summarising the status of action arising from the 28th TGC Meeting held on 24 January 2006. All requested actions had been completed and some items were reflected in the agenda of the current Meeting.

SUBCOMMITTEE REPORTS – SUBCOMMITTEE ON CHILD-RESISTANT PACKAGING

Minutes of Meeting 4 of the Child-Resistant Packaging Subcommittee

The TGC noted that its Subcommittee on Child-Resistant Packaging had held its fourth meeting on Monday 31 July 2006, and that the purpose of this meeting had been to consider stakeholder comments arising from the consultation on the draft ANZTPA Managing Director's Order relating to child-resistant packaging (CRP).

The TGC accepted the Report of the Subcommittee meeting and noted that discussion of its outcomes and recommendations would follow. The Chair and Members of the Subcommittee were thanked for their efforts in developing standards for CRP to be applied by ANZTPA.

RESOLUTION:

The Therapeutic Goods Committee ACCEPTS the Report of Meeting 4 of its Subcommittee on Child-Resistant Packaging, held on 31 July 2006.

Report on Stakeholder Consultation and Subsequent Subcommittee Recommendations

The TGC was advised that stakeholder consultation had been completed on the document *Draft Managing Director's Order Child-Resistant Packaging of Therapeutic Products under a Joint Australia New Zealand Therapeutic Products Agency* (draft CRP Order) and responses considered by the TGC's Subcommittee on Child-Resistant Packaging.

It was noted that the consultation documents had been provided directly to stakeholders in Australia and NZ, including industry associations, consumer organisations, government departments, government advisory committees, professional organisations and retail organisations. The documents also were placed on the ANZTPA website, with links from the TGA and Medsafe websites. In total, 33 submissions were received.

Following consideration of the issues raised in the stakeholder responses, the Subcommittee recommended a number of amendments to the draft CRP Order and also made a number of related recommendations for consideration by TGA/Medsafe/ANZTPA as appropriate.

The TGC was advised that the Subcommittee discussed at length whether there was a need for more rigorous requirements for non-reclosable packaging than had been proposed in the draft Order, and the feasibility and practicality of introducing such requirements. The packaging recommendations included in the report of the South Australian Coroner inquiring into the death of a two-year old child following ingestion of Kapanol capsules had been relevant to that discussion, as was the legislative status of requirements for child-resistant packaging in comparable overseas countries.

The Subcommittee recognised that making a substantive change to CRP requirements in the short-term would have profound implications for industry and has potential to adversely affect the availability of products in Australia and/or may result in the use of less desirable forms of packaging. The Subcommittee therefore preferred that a longer-term strategy for the improvement of standards for child-resistance of non-reclosable packaging be developed. The strategy proposed by the Subcommittee and subsequently supported by the TGC was as follows:

- Advice be provided to the TGA/Medsafe that the Subcommittee is committed to continuous improvement of standards of child-resistance for non-reclosable packaging;

- A recommendation be made that a Best Practice Guideline on non-reclosable packaging be developed, that will supplement the CRP Order;

- The Best Practice Guideline advise that industry should move towards increasing the robustness of this style of packaging and the protection against accidental poisoning that it provides to children. The Guideline should include reference to relevant overseas Standards and lists of packaging materials and/or systems deemed to be compliant. The Guideline should flag that ANZTPA will consider mandatory compliance with Standards in the future;

- Stakeholders be closely involved in the development of the Best Practice Guideline through stakeholder meetings in order to inform the process;

- The development process include a critical review of the data applicable to non-reclosable packaging and the incidence of child poisoning as well as a cost-benefit analysis;

- Consideration be given to inclusion in the Guideline of supporting background information and evidence relating to accidental childhood poisoning;

- Consideration be given to whether the introduction of mandatory requirements for non-reclosable packaging to comply with Standards for child-resistance should be phased-in for a limited number of substances or be applied more broadly in the first instance; and

- Development commence as early as possible following commencement of the ANZTPA and be coordinated by one of the Authority's expert advisory committees.

In relation to the draft CRP Order, the TGC supported amendments made by the Subcommittee to improve clarity and remedy some unforeseen implications identified by stakeholders. These included amendments to:

- emphasise that 'child-resistant' is not 'child-proof';
- correct the stated typical weight of an 18 month old child;
- remove the statement from the 'Introduction' concerning voluntary compliance with performance requirements of available international Standards for non-reclosable packaging, replacing it with a statement concerning the future development of a best practice guideline for non-reclosable packaging;
- clarify that the class entries given in the First Schedule are intended to apply only to Class 2 medicines, and that any Class 1 medicines warranting CRP would be listed individually instead;
- allow any size container intended solely as a dispensing pack and labelled as not for supply to patients to be exempt from CRP requirements;

- extend the general exemptions to small volume liquid or semi-solid preparations for application to the ear, and to pastes, powders or gels for the cleaning of teeth, as well as medicines to be used in a dental hospital or dental surgery;
- add definitions of 'Class 1 medicine', 'Class 2 medicine', 'dispensing pack', and 'export-only medicine';
- clarify the intent of the information contained in the footnote to the First Schedule through re-drafting and giving it greater prominence;
- replace the single entry for warfarin with a class entry for antithrombotic agents;
- extend a number of essential oil entries to capture combinations of essential oils where the total concentration of the combination exceeded a specified limit; and
- reduce the cut-off limit for ethanol from a total pack content of 5 g to 3 g on the basis of recalculation of a hazardous amount using the amended weight for an 18 month old child.

The following additional amendments were recommended by the TGC:

- re-titling of the Order to refer to 'medicines' rather than 'therapeutic products', with corresponding changes to terminology throughout the Order;
- replace definition of 'therapeutic product' with a definition of 'medicine'; and
- inclusion of relevant supplementary notes to provide plain English guidance on the requirements.

The TGC subsequently resolved:

RESOLUTION:

1. **The Therapeutic Goods Committee NOTES that:**

   - **stakeholder consultation on the document *Draft Managing Director's Order Child-Resistant Packaging of Therapeutic Products under a Joint Australia New Zealand Therapeutic Products Agency* (draft CRP Order) has concluded and responses have been considered by its Subcommittee on Child-Resistant Packaging;**

   - **in consideration of the stakeholder responses, the draft CRP Order has been amended by the Subcommittee; and**

   - **the Subcommittee has made a number of recommendations concerning related matters (labelling of transdermal patches containing opioids or nicotine, development of a best practice guideline concerning standards for non-reclosable packaging, and limits for iron compounds) for consideration by the Therapeutic Goods Administration/Medsafe and/or the Australia New Zealand Therapeutic Products Authority.**

2. **The Therapeutic Goods Committee RECOMMENDS that the draft CRP Order be re-titled to refer specifically to medicines, rather than therapeutic products.**

3. **The Therapeutic Goods Committee REFERS the draft CRP Order, as further amended by the Therapeutic Goods Committee, to the Joint Interim Expert Advisory Committee on Standards for consideration and finalisation.**

4. **The Therapeutic Goods Committee SUPPORTS the recommendations made by its Subcommittee on the following related matters and RECOMMENDS that these also be**

referred to the Joint Interim Expert Advisory Committee on Standards for consideration:

- **the need for the label of transdermal patches containing opioids or nicotine to include a statement regarding safe disposal after use;**
- **the need for development of a best practice guideline on non-reclosable forms of child-resistant packaging; and**
- **the need for a watching brief to be maintained on the harmonisation between Australia and New Zealand of scheduling of iron compounds, and possible consequential need for the cut-off limit for requiring child-resistant packaging to be reconsidered.**

5. **The Therapeutic Goods Committee REQUESTS that the Therapeutic Goods Administration draft a Supplementary Notes section for the draft CRP Order prior to its referral to the Joint Interim Expert Advisory Committee on Standards.**

SUMMARY AND STATUS OF THERAPEUTIC GOODS ORDERS

Members noted the summary of Therapeutic Goods Orders (TGO) included in the agenda papers indicating their status as either current or revoked. It also was noted that the current agenda included a number of items relating to specific Orders and their review.

MEDICINAL PRODUCTS

REVOCATION OF THERAPEUTIC GOODS ORDERS NO. 8 *STANDARDS ADOPTED FROM THE BRITISH PHARMACEUTICAL CODEX 1973* AND NO. 45 *AMENDMENTS OF THE SCHEDULE TO TGO8: "STANDARDS ADOPTED FROM THE BRITISH PHARMACEUTICAL CODEX 1973"*

The TGC considered stakeholder comment received on the proposed revocation of Therapeutic Goods Order No 8 *Standards adopted from the British Pharmaceutical Codex 1973* (TGO 8) and Therapeutic Goods Order No 45 *Amendments of the Schedule to TGO8: "Standards adopted from the British Pharmaceutical Codex 1973"* (TGO 45).

These Orders had been identified previously by the Committee as being outdated and it had been requested that stakeholders be consulted on implications of revocation.

The TGC was advised that stakeholder consultation had been undertaken by the TGA and key industry associations and sponsors of products identified as possibly being affected were specifically invited to comment. There was minimal response to the consultation, and no objections to, or concerns with, the revocation of TGO 8 and TGO 45 were raised. The TGC therefore resolved that:

RESOLUTION:

The Therapeutic Goods Committee RECOMMENDS the revocation of the following Therapeutic Goods Orders:

- **Therapeutic Goods Order No. 8 *Standards adopted from the British Pharmaceutical Codex 1973* (TGO 8); and**

- **Therapeutic Goods Order No. 45 *Amendments of the Schedule to TGO8: "Standards adopted from the British Pharmaceutical Codex 1973"* (TGO 45).**

ADOPTION OF BRITISH PHARMACOPOEIA 2005

The TGC noted that, as agreed at its previous Meeting, responses from stakeholders to the consultation on adoption of British Pharmacopoeia 2005 (BP 2005) as the edition of that publication referenced under the *Therapeutic Goods Act 1989* (the Act), had been considered out-of-session in April 2006. The TGC had subsequently recommended the adoption of BP 2005 on 1 July 2006 for the purposes of the edition of the British Pharmacopoeia defined under the Act.

The TGC was advised that an order giving effect to the TGC recommendation was signed by the Delegate of the Minister for Health and Ageing on 15 May 2006, and duly registered on the Federal Register of Legislative Instruments. The TGC therefore resolved:

RESOLUTION:

The Therapeutic Goods Committee NOTES:

- **its recommendation made out-of-session in April 2006 (RESOLUTION NO. OOS 2006/01) that the British Pharmacopoeia 2005 be adopted in Australia on 1 July 2006 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 15 May 2006 and duly registered on the Federal Register of Legislative Instruments.**

CONSEQUENTIAL CONSIDERATION OF TGO 70 *STANDARDS FOR EXPORT ONLY MEDICINES*

The TGC considered whether Therapeutic Goods Order No. 70 *Standards for Export Only Medicine* (TGO 70), which specifies alternate pharmacopoeial standards for export-only medicines, should be updated to also refer to the most recent editions of the various pharmacopoeias. The TGA had undertaken consultation with relevant stakeholder groups on a proposal to amend TGO 70 in order to update the referenced edition of the British Pharmacopoeia to the 2005 edition.

The TGC noted that few comments were received, the only substantive one suggesting that export-only products should be allowed to comply with standards in superseded pharmacopoeias, provided this was acceptable to the importing country.

The TGA had subsequently responded that it was expected that export medicines meet the same standards as applicable to products approved for supply in Australia and allowing products to comply with outdated standards was not acceptable. This provided a safeguard for consumers in importing countries, and provisions already existed for exemptions from standards to be considered on a case by case basis.

Although the TGC endorsed the TGA position, the Committee discussed the philosophical issue of whether it should be acceptable for products to remain compliant with the standard current at the time of product approval, rather then being required to update to the standard given in new editions of pharmacopoeias. This issue was relevant to the application of pharmacopoeial standards by ANZTPA.

Members provided a number of relevant comments for consideration by the agencies in developing trans-Tasman standards. The TGC subsequently recommended:

RESOLUTION:

The Therapeutic Goods Committee RECOMMENDS that:

- **Therapeutic Goods Order No. 70 *Standards for Export Only Medicines* (as amended by TGO 70A) be amended to update the reference to all four pharmacopoeias as follows:**
  - **British Pharmacopoeia 2002 be amended to British Pharmacopoeia 2005;**
  - **European Pharmacopoeia 4th Edition be amended to European Pharmacopoeia 5th Edition, including Supplements 5.1 to 5.6 inclusive;**
  - **United States Pharmacopeia 26th Edition be amended to United States Pharmacopeia - National Formulary USP 29 – NF 24; and**
  - **Japanese Pharmacopoeia 14th Edition be amended to Japanese Pharmacopoeia 14th Edition including Supplement I and Supplement II; and**
- **Export medicines should meet standards for quality equivalent to those for the domestic market.**

UPDATE ON LABELLING REQUIREMENTS FOR MEDICINES UNDER ANZTPA

The TGC was provided with an update on progress in the finalisation of proposed labelling requirements for medicines to be applied under ANZTPA. The release of an updated version of the ANZTPA draft labelling Order on the ANZTPA website together with a report on the previous stakeholder consultation was noted. It was advised that responses were now being reviewed by the TGA/Medsafe, and the final draft Labelling Order would be among the suite of draft instruments to be released for final consultation in March 2007.

STAKEHOLDER CONSULTATION ON MICROBIOLOGICAL STANDARDS FOR MEDICINES UNDER ANZTPA

The TGC noted an invitation to provide comment on the consultation document *Microbiological Standards for Medicines in the Australia New Zealand Therapeutic Products Authority (ANZTPA)*

which set out proposed microbial standards for medicines to be applied under ANZTPA. The closing date for comments was 15 September 2006.

The TGC noted the proposals contained in the consultation document and the background information provided by a TGA officer.

BLOOD AND TISSUES

No items.

MEDICAL DEVICES

THERAPEUTIC GOODS ORDER NO. 64 *STANDARD FOR TAMPONS – MENSTRUAL* (TGO 64) – SUBMISSION REGARDING TAMPON ABSORBENCY TEST METHODOLOGY

The TGC received for consideration a submission from XXXXXXXX seeking an amendment to Therapeutic Goods Order No. 64 *Standard for Tampons – Menstrual* (TGO 64) to permit the use of an alternate absorbency test methodology.

TGO 64 determined that the matters specified in the Australia New Zealand Standard AS/NZS 2869:1998 *Tampons – Menstrual* constituted the standard for menstrual tampons in Australia, subject to an additional requirement concerning sampling and number of non-compliers. It had been amended in September 2001 to require the addition of a new clause to the information leaflet enclosed in the primary pack. AS/NZS 2869:1998 *Tampons – Menstrual* specified permissible materials from which tampons may be manufactured, design requirements, performance requirements, microbial content limits, packaging requirements and marking requirements (including absorbency labelling) and provided a number of test methodologies including one for determination of absorptive capacity.

The submission from XXXXXXXX sought to have TGO 64 amended to allow the use of the EDANA test methodology for determining absorptive capacity, as applied in the European Union and the US FDA Manufacturing Requirements.

The TGC took into consideration the regulatory history of tampons in Australia, including a fatal case of Toxic Shock Syndrome (TSS) associated with the use of tampons, and subsequent actions by Standards Australia and the TGA. The Committee also noted advice on the intricate relationship between absorbency labelling, actual absorbency, the risk of TSS and the importance of correct tampon selection for the particular level of menstrual flow.

In relation to a comparison of the two absorbency test methods provided by XXXXXXXX, the TGC noted that the EDANA/FDA test method appeared to more closely simulate *in vivo* data than the existing test method, and if considered in isolation from the existing test method and associated labelling requirements, had merit. However a key issue was the finding that, for tampons of the same specification, the EDANA/FDA test method yielded a substantially lower absorbency value to that obtained using the test method stipulated by AS/NZS 2869:1998/TGO 64. While the magnitude of the difference depended on the absorbency of the tampon, the difference could result in equivalent products being classified differently depending on which test methodology was used.

Alternatively the amount of fibre in a tampon could be adjusted in order for the tampon to meet the same nominal absorbency. In this latter situation, those tampons tested using the EDANA methodology would be more absorbent in real terms and therefore could potentially remain *in situ* for longer - thus increasing the risk of TSS. This was a safety consideration.

Furthermore, the TGC considered that the introduction of an alternative test methodology which gives different absorbency results to those obtained using the existing methodology would potentially reduce the value of current Australian absorbency labelling, while the introduction of a second system for absorbency labelling would potentially cause confusion for consumers.

The TGC concluded that it would not be appropriate for TGO 64 to allow the use of alternate test methodologies that would result in different test results, and that the most appropriate mechanism for XXXXXXXX to follow in order to pursue acceptance of the EDANA/FDA test methodology would be to refer the proposal directly to Standards Australia, with the aim of having the methodology in AS/NZS 2869:1998 *Tampons – Menstrual* reviewed. Label statements of absorbency and implications for consumers would necessarily be part of such consideration by Standards Australia. The TGC therefore resolved:

RESOLUTION:

1. **The Therapeutic Goods Committee NOTES:**

   - **the submission made by XXXXXXXX seeking amendment to Therapeutic Goods Order No. 64 *Standard for Tampons – Menstrual* (TGO 64), in order to permit the use of an alternate absorbency test methodology, namely the EDANA/FDA methodology; and**

   - **the advice provided on this issue by the Therapeutic Goods Administration.**

2. **The Therapeutic Goods Committee SUPPORTS the principle that Australia should not apply unique requirements to therapeutic goods except where this can be justified.**

3. **The Therapeutic Goods Committee CONSIDERS that:**

   - **a Therapeutic Goods Order should not permit the use of alternate methodologies that lead to different test results;**

   - **the use of different test methodologies to determine tampon absorbency can result in different absorbency ratings for the same tampon;**

   - **use of the EDANA test methodology in place of the methodology specified in the Australia New Zealand Standard AS/NZS 2869:1998 *Tampons – Menstrual*, which is adopted by TGO 64, without corresponding changes to absorbency classifications, would potentially result in an increase in the weight of fibre in tampons in order to achieve the same stated absorbency, and hence result in an increase in the actual absorbency of tampons in Australia;**

   - **such an increase in absorbency, without corresponding changes to labelling, would have potential to increase the risk of Toxic Shock Syndrome among users; and**

- **there also would be potential for significant consumer confusion associated with the introduction of a second or replacement scheme for absorbency labelling.**

4. **The Therapeutic Goods Committee RECOMMENDS that:**

- **Standards Australia should be requested to consider amending the test method given in Australia New Zealand Standard AS/NZS 2869:1998 *Tampons – Menstrual* to take into account the information provided by XXXXXXXX concerning the EDANA test methodology; and**

- **Any changes made to the test methodology in the Australia New Zealand Standard should take into account consequences in relation to:**
  - **the absorbency of the tampon; and**
  - **labelling requirements for tampons marketed in Australia.**

PROPOSED REVOCATION OF THERAPEUTIC GOODS ORDER NO. 47 *BARIUM LIME* (TGO 47)

The TGC noted that Therapeutic Goods Order No. 47 *Barium lime* (TGO 47) determined that the standard for barium lime was the monograph entitled 'Barium Hydroxide Lime' of the United States Pharmacopoeia. The TGC had previously commented that the use of barium lime had been discontinued for safety reasons and products were no longer available in Australia. The TGO may therefore be irrelevant.

The TGC now received a report prepared by the TGA on the use of barium lime as a carbon dioxide absorbent in anaesthesia which confirmed that barium lime was no longer used in anaesthetic equipment for safety reasons, and therefore a TGO stipulating its quality and performance was no longer required. The TGC therefore recommended that:

RESOLUTION:

The Therapeutic Goods Committee RECOMMENDS the revocation of Therapeutic Goods Order No. 47 *Barium Lime.*

THERAPEUTIC GOODS ORDER NO. 59 *POLYMER URETHRAL CATHETERS FOR GENERAL MEDICAL USE*

The TGC considered whether Therapeutic Goods Order No. 59 *Polymer Urethral Catheters for General Medical Use* (TGO 59) remained a relevant regulatory tool and/or should be reviewed. TGO 59 adopted, with minor amendment, the provisions of the Australia New Zealand Standard AS/NZS 2696:1996 *Medical devices – Polymer urethral catheters for general medical use* as the standard for polymer urethral catheters. However Standards Australia had recently withdrawn AS/NZS 2696:1996.

The TGC noted advice from the TGA that, until the end of the transition period in October 2007 for the new medical device regulatory scheme, the most appropriate Standard for polymer urethral catheters was AS/NZS 2696:1996. Thus TGO 59 remained relevant. Nevertheless, the TGA was seeking legal advice as to whether continued reference in a legislative instrument to a Standard that

had been withdrawn presented any legal difficulties. It was noted that the TGA also had requested Standards Australia to reconsider the status of AS/NZS 2696:1996. The TGC therefore resolved:

RESOLUTION:

1. **The Therapeutic Goods Committee NOTES that:**

   - **Therapeutic Goods Order No. 59 *Polymer Urethral Catheters for General Medical Use* (TGO 59) determines that the standards for polymer urethral catheters for general medical use are those specified in Clauses 1 to 10 inclusive and Appendices A and B of the document titled "AS/NZS 2696:1996 Australian/New Zealand Standard, *Medical devices – Polymer urethral catheters for general medical use*" published by Standards Australia on 5 July 1996; and**

   - **AS/NZS 2696:1996 was withdrawn by Standards Australia with effect 28 October 2005.**

2. **The Therapeutic Goods Committee CONSIDERS that the standards given in AS/NZS 2696:1996, as adopted by TGO 59, remain relevant to the regulation of polymer urethral catheters for general medical use as medical devices.**

3. **The Therapeutic Goods Committee RECOMMENDS that:**

   - **the Therapeutic Goods Administration seek legal advice on whether TGO 59 can refer to a withdrawn Australian Standard and therefore be retained without change until the end of the transition period for the new regulatory system for medical devices in October 2007; and/or**

   - **explore with Standards Australia the possibility of AS 2696:1996 being re-instated as current until October 2007; and**

   - **advice on these matters be referred back to the Committee for consideration at its next Meeting.**

THERAPEUTIC GOODS ORDER NO. 63 *STANDARD FOR STERILE THERAPEUTIC GOODS* (TGO 63)

The TGC noted that Therapeutic Goods Order No. 63 *Standard for Sterile Therapeutic Goods* (TGO 63) determined that the requirements specified in British Pharmacopoeia 1998, Appendix XVI – Tests for Sterility [European Pharmacopoeia, Supplement 1998, Biological Tests-Sterility] constituted the standard for therapeutic devices that were labelled as sterile or sterilised or otherwise purported to be sterile or sterilised. The TGC had previously noted that TGO 63 would be relevant to some existing products until the end of the medical devices transition period in October 2007.

As the edition of the BP now adopted under the *Therapeutic Goods Act 1989*, British Pharmacopoeia 2005 (BP 2005), contained an updated appendix on sterility testing, the TGC considered whether TGO 63 should be revoked or updated to include reference to the latest edition of the BP.

The TGC noted a technical comparison between the BP 1998 and the now harmonised Test for Sterility as published in BP 2005, Ph Eur 5.6 and the USP 29 -NF 24. This demonstrated that the differences between BP 1998 and BP 2005 were relatively minor and these relatively minor differences were not regarded by the TGA Laboratories as sufficient to present a problem in taking regulatory action if a sterile device failed the test for sterility. Legal advice was again being sought to confirm this.

The TGC concluded that, as TGO 63 would no longer be required after October 2007, and the current reference to BP 1998 did not appear to present any difficulties for the product regulator, revision of TGO 63 was not warranted at this time. However Medical Device Standards Order No. 3 (MDSO3) should be updated. The TGC therefore resolved:

RESOLUTION:

The Therapeutic Goods Committee:

- **NOTES that Therapeutic Goods Order No. 63 *Standard for Sterile Therapeutic Goods* (TGO 63) remains relevant to the regulation of sterile therapeutic devices until 4 October 2007, which marks the end of the transition period for the new regulatory system for medical devices;**

- **NOTES that TGO 63 should be retained without amendment until the end of that transition period, as reference to test requirements for sterility specified in Appendix XVI of British Pharmacopoeia 1998, rather than the requirements specified in the current edition of the British Pharmacopoeia, is of little practical consequence in the short term; and**

- **RECOMMENDS that Medical Device Standards Order No. 3 be revised to refer to the updated version of the *TGA Guidelines for Sterility Testing of Therapeutic Goods (2006)* for medical devices that are required to be subjected to end-point sterility testing for conformance with Essential Principle 8.3(3).**

OTHER MATTERS

CODE OF GOOD WHOLESALING PRACTICE FOR THERAPEUTIC GOODS FOR HUMAN USE – CONSULTATION RESPONSES

The TGC considered comments received from stakeholders as a result of the consultation on a draft revision to the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* (cGWP).

The TGC noted that a number of stakeholders identified parts of the draft Code which would benefit from technical and/or editorial amendment. The TGC further noted a number of policy matters relating to the Code and its application had been raised by stakeholders, indicating that further consideration and refinement was needed.

The XXXXXXXX and the XXXXXXXX were among the stakeholder organisations providing comment on policy matters, and this drew attention in particular to implications of the cGWP to obligations on wholesalers under the 4th Community Pharmacy Agreement and associated

Community Service Obligation (CSO) arrangements for the supply of Pharmaceutical Benefits Scheme medicines. The XXXXXXXX and the XXXXXXXX considered that the Compliance Requirements and Service Standards of the CSO must be taken into consideration before finalisation of the revision to the cGWP, and XXXXXXXX members were concerned with potential additional costs associated with achieving compliance with an updated Code.

Although the TGC was able to address most comments relating to technical aspects of the draft Code and the suggested editorial changes, the Committee considered that, in view of the responsibility for application of the cGWP being with the States and Territories, the policy matters raised by stakeholders must be referred to the National Coordinating Committee on Therapeutic Goods (NCCTG) for resolution. These policy matters would direct the further development of the Code. The TGC theref6re resolved as follows:

RESOLUTION:

1. **The Therapeutic Goods Committee NOTES that:**

   - **Stakeholder consultation on the draft revision to the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* has been undertaken;**

   - **Stakeholders have identified some parts of the draft Code which would benefit from technical and/or editorial amendment; and**

   - **Some stakeholders have raised policy matters relating to the Code, indicating that further refinement may be needed.**

2. **The Therapeutic Goods Committee:**

   - **AGREES to a number of amendments to the technical aspects of the draft Code that take account of the stakeholder comments, as discussed, as well as editorial changes; and**

   - **CONSIDERS that, in view of the application of the Code by the States and Territories, those issues raised by stakeholders relating to policy should be referred back to the National Coordinating Committee on Therapeutic Goods (NCCTG) for resolution, and then finalisation of the Code.**

3. **The TGC has identified the following matters raised by stakeholders as being matters that require consideration and resolution by the NCCTG:**

   - **application of the Code to third party logistics providers;**

   - **scope of the Code in terms of which therapeutic goods it applies to (pharmaceuticals, scheduled medicines, medical devices, IVDs etc), and whether the same requirements are relevant to all;**

   - **the need for further consideration of, and delineation between, those stated requirements that are mandatory and those that should be advisory only, including the meaning of the terms 'should', 'shall' and 'must';**

- **whether the Code is to also cover movement of therapeutic goods from retail level back to wholesaler where goods are returned;**
- **the inclusion of provisions for batch traceability to retail level;**
- **implications of the Code to arrangements for the supply of Pharmaceutical Benefit Scheme medicines, and obligations on wholesalers under the 4th Community Pharmacy Agreement and associated Community Service Obligation (CSO) arrangements;**
- **implementation by States and Territories, including transition from the existing Code; and**
- **application in the context of the proposed Australia New Zealand Therapeutic Products Authority.**

4. In relation to batch traceability, the Therapeutic Goods Committee CONSIDERS that the ability of wholesalers to batch trace to retail level would be of benefit in the management of product recalls. The Therapeutic Goods Committee therefore RECOMMENDS that the NCCTG develop a strategy for inclusion in the Code that will require wholesalers to move towards implementing batch recording.

CLOSE OF MEETING

There being no further business, the Chair closed the Meeting at 4:00pm and thanked Members for their attendance.