TGA THERAPEUTIC GOODS ADMINISTRATION

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Commonwealth Department of Health and Ageing

Therapeutic Goods Committee
19th Meeting (8 November 2001)

Information for Stakeholders – Report on Meeting

The 19th Meeting of the Therapeutic Goods Committee (TGC) was held in Conference Room 1, Ground Floor, TGA Building, Narrabundah Lane, Symonston on 8 November 2001, commencing at 9.30 a.m. and closing at 4.00 p.m.

Present

TGC Members:

Professor Stella O'Donnell (Chair)
Mr David Clayton
Associate Professor Loraine Holley
Professor Bruce Milthorpe
Dr John Russell
Ms Anthea Steans

TGA officers:

Ms Rita Maclachlan
Dr Susan Alder
Ms Siepie Larkin (part Meeting)
Mr Bob Tribe (part Meeting)
Dr David Randles (part Meeting)
Dr David Briggs (part Meeting)
Ms Sharyn McGregor (part Meeting)

Secretariat:

Ms Lyn Lewis
Ms Fiona Mildner

Apologies:

Mr Philip Daffy
Professor Milton Hearn
Mr Barry Evers-Buckland

AGENDA AND COMMITTEE ADMINISTRATION

Opening of Meeting – Welcome and Apologies

The Meeting was opened at 9.30 am. Members were welcomed and apologies from absent Members were noted. The Committee was advised that a number of TGA officers would be present for particular items of discussion as the Meeting progressed.

Adoption of Agenda

Members noted the agenda as presented and raised no issues in relation to its adoption.

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.

Out-of-Session Ratification and Status of Resolutions and Minutes

The Therapeutic Goods Committee (TGC) established processes to allow ratification of Minutes of TGC Meetings out-of-session, and the rapid public release of key outcomes from Meetings. The TGC considered that this action was necessary because of the potential impact of the Committee's recommendations on a wide range of stakeholders. Additionally, public release would be in accordance with the principles of transparency and accountability under which the Committee operates.

RESOLUTION NO. 19/1

The Therapeutic Goods Committee endorses the introduction of a process to achieve ratification of Minutes out-of-session, based on:

(1) Within 20 working days of the Meeting, distribution of draft Minutes to all Members;

(2) Within 10 working days, submission to the Secretariat, by Members who attended that Meeting, of comments on the draft Minutes;

(3) Within 5 working days, circulation to all Members of comments received (other than typographical corrections and changes of editorial nature), details of amendments made (if any) and a copy of the amended Minutes;

(4) Within 5 working days, provided that the Secretariat has received confirmation by majority of Members present at the Meeting that the Minutes as amended (point 3) are a true record of that Meeting, the Chair may sign them as a true record;

(5) If objections are received to the amended Minutes, the Chair may, at his/her discretion, defer ratification of the Minutes to the next formal Meeting of the Committee.

RESOLUTION NO. 19/2

That with every Resolution made by the TGC, the TGC recommends whether that Resolution should be made public or not.

RESOLUTION NO. 19/3

(1) TGC recommends that, at the earliest possible time, the TGA make public:
- **(a) an edited version of the Resolutions made by the TGC; and**
- **(b) an edited version of the TGC ratified Minutes.**

(2) For the purposes of this Resolution, 'edited' means:
- **(a) deletion of:**
  - **(i) trade secrets and/or commercial-in-confidence information;**
  - **(ii) reference to whether agreement was unanimous or not;**
  - **(iii) reference to whether or not a Member was present at the time of a vote, unless it relates to a conflict of interest;**
  - **(iv) any reference that will personally identify Members, unless it relates to a conflict of interest; and**
  - **(v) any other information for which public disclosure is inappropriate.**
- **(b) in the case of a conflict of interest, the Member's name and the Committee's handling of the conflict is to be retained.**

Note: A Member has the right to request disclosure of their name in relation to any item.

Minutes of the 18th Meeting of TGC

Members noted that the draft Minutes of the 18th Meeting had been circulated previously to Members for comment, and as a consequence, some minor editorial amendments made. Members now agreed to the formal ratification of the Minutes as included in the agenda and recommended that they be signed by the Chair as a true and accurate record of the 18th Meeting.

RESOLUTION NO. 19/4

The Minutes of the 18th Meeting of the Therapeutic Goods Committee held by teleconference on 14 June 2001 be signed by the Chair as a true and accurate record of that Meeting.

Subcommittee on Manufacturing Principles

The Committee agreed to establish a Subcommittee to consider a replacement for the current *Australian Code of Good Manufacturing Practice for Therapeutic Goods (Medicinal Products),* which was now over 10 years old. Consultation between the TGA and stakeholders on the adoption of one of two existing international guides (the Pharmaceutical Inspection Co-operation Scheme (PIC/S) *Guide to Good Manufacturing Practice for Medicinal Products,* and the European Commission's *Guide To Good Manufacturing Practice for Medicinal Products)* had commenced, and the Subcommittee was to be requested to explore the options in more depth and advise on associated issues such as transition periods, training for industry and ongoing review processes.

The TGC rescinded an earlier resolution (Resolution 16/6) from September 1999 recommending that a similar subcommittee be established on an *ad hoc* basis only.

RESOLUTION NO. 19/5

The TGC rescinds Resolution 16/6 of the 16th meeting of the TGC in relation to the *Ad Hoc* Subcommittee on GMP.

RESOLUTION NO. 19/6

The TGC establishes a Subcommittee on Manufacturing Principles:

(1) The Terms of Reference of the Subcommittee to be:

To advise the TGC on the principles to be observed in the manufacture of therapeutic goods for human use.

(2) The composition of the Subcommittee to consist of the following members:

A member of the TGC who shall Chair the Subcommittee;
One nominee of the TGA;
A representative of each of the following industry organisations: APMA, ASMI, CHC and MIAA.

(3) The Subcommittee may co-opt other members as required to advise on particular matters.

(4) The Secretary of the TGC is to be the Secretary of the Subcommittee.

MEDICINAL PRODUCTS

Adoption of British Pharmacopoeia 2001

Following consultation with the peak medicine and medical device industry bodies, the TGC recommended that the definition of the British Pharmacopoeia (BP), referenced under section 3 of the *Therapeutic Goods Act 1989* as the principle standard, be updated to the British Pharmacopoeia 2001 (BP 2001) with effect 1 December 2001.

RESOLUTION NO. 19/7

(1) The Therapeutic Goods Committee recommends the adoption of the British Pharmacopoeia 2001 on 1 December 2001 for the purposes of the editions of the British Pharmacopoeia defined under the *Therapeutic Goods Act 1989*.

(2) The Committee will consider out of session the adoption of Amendment 1 to British Pharmacopoeia 2001 following consultation by the TGA with the peak medicine and medical device industry groups.

Standards for Ethanol – Review of Requirement to Maintain TGO 29

The TGC reviewed the need to retain the current Therapeutic Goods Order defining the standard for ethanol when used in the manufacture of pharmaceuticals (Therapeutic Goods Order No. 29 *Standards for Ethanol* – TGO 29). This TGO was made in 1986, at which time major Australian distilleries were unable to comply fully with the requirements of the British Pharmacopoeia (BP). Revocation of TGO 29 would result in the default standard becoming that given in the edition of the BP defined under the Act.

Advice received from the major distilleries indicated that this was no longer the case as production processes and analytical techniques had advanced. Three of the four Australian distilleries supplying ethanol for pharmaceutical use indicated that the ethanol produced would, or could, comply with BP 2001. On this basis, it was considered likely that revocation of TGO 29 would have little, if any, impact on the pharmaceutical industry. The TGC therefore recommended that stakeholder consultation be undertaken with a view to revoking TGO 29.

RESOLUTION NO. 19/8

The Therapeutic Goods Committee recommends that the TGA consult with stakeholders, with a view to obtaining agreement to the revocation of Therapeutic Goods Order No. 29 'Standards for Ethanol'.

Standards for Export Only Medicines – Proposed New TGO

The TGC supported a proposal to create a new Therapeutic Goods Order specifying alternative standards to which medicines for export only may comply. The proposal had arisen from *The Review of the Regulatory Regime for the Export of Therapeutic Goods.* The

new TGO would give sponsors of medicines for export only the option of compliance with requirements of the British Pharmacopoeia or range of alternative, but comparable, standards. This option would provide for more timely approval of products for export and remove an obstacle to Australian manufacturers competing on the international market.

While the alternative standards proposed for adoption were the current editions of the British Pharmacopoeia, the United States Pharmacopeia, the Japanese Pharmacopoeia and the European Pharmacopoeia, the TGC noted that the Order would need regular maintenance to ensure it referenced the most recent editions of each.

RESOLUTION NO. 19/9

> **The Therapeutic Goods Committee recommends the adoption of the Therapeutic Goods Order "Standards for Export Only Medicine" and the inclusion in this Order of the following alternate standards for medicine manufactured in Australia, or imported into Australia, for export only subject to the conditions given in the Order:**
>
> **(1) The British Pharmacopoeia (current edition);**
>
> **(2) The United States Pharmacopoeia (current edition);**
>
> **(3) The Japanese Pharmacopoeia (current edition); and**
>
> **(4) The European Pharmacopoeia (current edition).**

Gluten and TGO 69

In relation to Therapeutic Goods Order No. 69 *General requirements for labels for medicines* (TGO 69) that had been gazetted on 12 September 2001, the TGC considered a request for advice on a suitable test for detecting the presence of gluten. This request related to the requirement in TGO 69 for the presence of gluten in products to be declared on labels and the statement in the First Schedule to the TGO that a medicine can be regarded as 'gluten free' if it contains no detectable gluten and no oats or malt.

While TGC and TGA did not wish to specify a lower limit for gluten, or stipulate any particular method for testing, an acceptable test method was noted to be the most recent update of the AOAC method, an earlier version of which had been specified in the previous Food Standards Code. This method was:

> *Association of Official Analytical Chemists International, AOAC Official Method 991.19 Gliadin as a Measure of Gluten in Foods, Official Methods of Analysis of AOAC International , 17th edition, Association of Official Analytical Chemists International, Maryland, 2000.*

Child Resistant Packaging – Progress Towards a New TGO

The Committee considered progress in the development of a new Therapeutic Goods Order on child-resistant packaging to replace the two existing, but outdated, Orders on this matter (TGO 20 *Child Resistant Containers* and TGO 33 *Amendment of Schedules to Therapeutic Goods Order No. 20 Child Resistant Containers*).

While the TGC's Subcommittee on Child Resistant Packaging had made considerable progress in reviewing requirements, a number of technical issues remained to be resolved before drafting of the new Order could be finalised. The TGC recommended that the Subcommittee reconvene as soon as possible for this purpose.

RESOLUTION NO. 19/10

The Therapeutic Goods Committee recommends that the Subcommittee on Child-Resistant Packaging be re-convened:

(1) to consider recent technical matters that have emerged regarding the proposed TGO on child-resistant packaging; and

(2) to report back to the next TGC Meeting.

Harmonisation of Australian Approved Names Associated with the Adoption of BP 98

The Committee considered the ongoing issue of harmonisation of Australian Approved Names for chemical substances with International Non-proprietary Names, which had arisen from a change in the nomenclature used in the British Pharmacopoeia in compliance with a European Economic Community Directive. This was an important issue as it would impact on a vast range of stakeholders, not only regulatory authorities and industry but also health professionals, education institutions, and consumers. Issues in relation to trans-Tasman harmonisation and implications across the Health portfolio also needed to be taken into account.

The Committee recommended that the TGA progress this matter as a priority. In the interim, in order to prevent misinterpretation of a previous recommendation of the Committee concerning the use of dual names on labels of medicines, the TGC agreed that Resolution 16/9 from its 16th Meeting should be rescinded. It was noted that the Committee's view on dual naming was not fixed, and this particular issue would be reconsidered after there had been further discussion with industry.

RESOLUTION NO. 19/11

The TGC rescinds Resolution 16/9 from the 16th Meeting of TGC held on 22 June 2000.

RESOLUTION NO. 19/12

The TGC recommends that the TGA progress:

(1) strategies for adopting the International Non-Proprietary Names that appear in the BP; and

(2) provision of a transition process acceptable to industry and other stakeholders.

Review of Therapeutic Goods Orders Created Prior to 1990

The TGC noted that the necessary administrative processes for revocation of five Therapeutic Goods Orders relating to veterinary products, which the National Registration Authority for Agricultural and Veterinary Chemicals had advised were no longer required, were being undertaken by the TGA. These TGOs were: 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*; and TGO 30 *Standards Adopted from the British Pharmacopoeia (Veterinary) 1985, the British Pharmacopoeia (Veterinary) 1977 and the British Veterinary Codex 1965, Supplement 1970.*

Revocation of these TGOs had been recommended by the TGC at its 18th Meeting in June 2001, as had revocation of TGO 25 *Standard for Hydrocortisone Acetate Eye Ointment and Ear Ointment* provided the sponsor of the only affected product was consulted and the product marketed was of satisfactory quality.

The TGC noted that review of TGO 8 *Standards Adopted from the British Pharmaceutical Codex 1973*, as amended by Therapeutic Goods Order No. 45 *Amendments of the Schedule to Therapeutic Goods Order No 8 "Standards Adopted from the British Pharmaceutical Codex 1973"* was ongoing.

MEDICAL DEVICES

The TGC noted:

- A report on progress in the establishment of the new regulatory system for medical devices;
- Advice of gazettal of Therapeutic Goods Order No. 64A *Amendment to TGO 64: Standard for Tampons – Menstrual*, a new Order requiring inclusion of an additional warning statement in tampon package inserts or patient information leaflets; and
- Progress in adoption of a new International Standards Organisation standard for dental materials through development of a new Therapeutic Goods Order.

OTHER MATTERS

The TGC noted an update on work towards the establishment of a joint Australia-New Zealand regulatory agency for therapeutic goods.

CLOSE OF MEETING

The Chair thanked Members for their participation and closed the Meeting at 4.30 pm. It was agreed that the date of the next Meeting would be determined out-of-session.

The Minutes of the Meeting were signed by the Chair as a true and correct record of the Meeting on 5 January 2002.