Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on the Safety of Medical Devices

Meeting statement

Meeting 9 – 9 April 2015

Role of the Advisory Committee on the Safety of Medical Devices (ACSMD) in the TGA's regulatory decision making process

The ACSMD is a statutory advisory committee established by the Therapeutic Goods Regulations 1990.

The TGA currently has ten statutory advisory committees from which it can obtain independent expert advice on specific scientific and technical matters to aid the TGA's regulatory decision making and other regulatory processes.

The ACSMD provides advice to the TGA on, amongst other things, matters relating to the safety, risk assessment, risk management and performance of medical devices supplied in Australia.

How this statement should be read

The advice provided by the ACSMD is an important element in the undertaking of the regulatory functions of the TGA. However, it forms only one part of the total body of information that is available to, for instance, a TGA delegate making a regulatory decision under the *Therapeutic Goods Act 1989* ("the Act"). Therefore, while appropriate consideration will be given to such advice, it is important to note that neither the TGA nor a TGA delegate is obliged to follow it.

It should also be noted that details of the committee's advice may not become publicly available for some time after the committee has provided that advice. The purpose of this Meeting Statement is to describe in general terms the matters considered by the committee at each meeting and for it to be available as soon as reasonably practical after the relevant meeting.

Additionally, following publication of this statement, it is most likely that further work will be undertaken by the TGA to investigate, monitor and / or evaluate the medical devices considered by the ACSMD; and this will continue for some time into the future. It is therefore possible that further information about the medical devices will become publicly available at a later time and this will be pursuant to a regulatory decision under the Act being made and following further consultation with the device's sponsor and / or manufacturer.

Overview of the medical devices referred for advice

The TGA continually monitors medical devices supplied in Australia to ensure their ongoing safety, quality and performance (as the manufacturer intended). As part of this process, the TGA routinely undertakes safety reviews of medical devices, seeks advice on proposed safety reviews and Risk Management Plans and also undertakes post-market monitoring of medical devices.

Safety reviews

At this meeting, the committee's advice was sought on two safety reviews concerning the usability of insulin infusion pumps and the durability of balloon anchors in gastrostomy feeding devices.

Insulin infusion pumps

The committee noted that the TGA has received Device Incident Reports (DIRs) concerning insulin infusion pumps for a variety of reasons and that a preliminary review had indicated that the number of DIRs for insulin infusion pumps appeared to be increasing compared to other Class IIb devices.

Specifically, the committee was asked to provide advice on the ongoing risk-benefit ratio as well as whether these kinds of devices continue to meet the specified Essential Principles for insulin infusion pump devices. The committee advised that systematic review of randomised controlled trials have shown that insulin pumps were not inferior in terms of efficacy or safety when compared to multiple daily injections (MDI) but there was not enough conclusive evidence to support that pumps were superior in any age group.

In addition to clinical markers, patient experience was very important in consideration of the risk-benefit ratio. An important point that was highlighted by a member was that self-management of type 1 diabetes was a demanding, fatiguing and chronic task. Insulin pumps may offer an appropriate therapeutic option in certain individuals, by reducing the burden of disease management.

While technical pump malfunction cannot be excluded, many adverse events are likely to be related to user 'error'. Training patients and their families on insulin pump use is necessary to reduce the risk of adverse events. Periodic skill retesting and re-training with new pump models is also needed.

The committee also advised that increasing numbers of adverse event reports were likely, at least in part, to be due to the increasing use of pumps. For example, a report by the Australian Institute for Health and Welfare (AIHW)[1] states that uptake of insulin pump therapy had increased from 107 per month in 2004 to 140 per month in 2010. This growth in usage should be considered in reviewing changes in the numbers of adverse event reports. Differences in the rates of adverse events relating to different manufacturers/pumps may also be explained by differences in market share.

The committee also advised that the TGA may wish to approach Diabetes Australia and via its professional section (the Australian Diabetes Society) to request input into further improving pump guidelines and to further improve reporting of apparent pump malfunction.

[1] Australian Institute of Health and Welfare 2012. Insulin pump use in Australia. Diabetes series no.18. Cat. no. CVD 58. Canberra: AIHW.

Gastrostomy feeding devices

The committee noted that gastrostomy feeding devices included on the Australian Register of Therapeutic Goods (ARTG) have been the subject of Device Incident Reports (DIRs). Specifically, the committee was asked to provide advice on the ongoing risk-benefit ratio for the balloon type of anchor over the flange type; and whether the committee had an opinion on an acceptable failure rate?

Any device will fail eventually, and the committee noted the higher number of DIR reports for balloon devices compared to flange devices. However, there did not appear to be robust statistics to compare the flange and balloon types. Based on available evidence, the committee was unable to form an opinion on an acceptable failure rate of the percutaneous endoscopic gastrostomy (PEG) device.

The literature reviewed by the committee lacked evidence on which to propose an appropriate life span for the PEG device. Clinical experience suggested that the balloon type tended to last for months and the flange type lasted a couple of years. Nonetheless, the benefits associated with ease of replacement and removal of the balloon anchored device, when no longer required, outweighs the risk of perceived early balloon failure.

Proposed safety reviews

At this meeting, the committee's advice was also sought on two proposed safety reviews concerning Groshong Peripherally Inserted Central Catheters (PICC) and whether there is an association between Toxic Anterior Segment Syndrome (TASS) and Alcon ophthalmic devices.

Groshong Peripherally Inserted Central Catheters (PICC)

The committee noted that all Peripherally Inserted Central Catheters (PICCs) are associated with a relatively high rate of infectious, thrombotic, and mechanical complications. Catheter breakage is a potentially serious event, as the indwelling portion of the catheter can embolise and migrate into the heart or lungs.

The TGA's Device Incident Report Investigation Scheme (IRIS) database contains reports linked to the Groshong PICC. Half of the reports relate to fracture of the catheter. Testing this catheter to check its compliance with the tensile test requirements set down in the relevant International Standard disclosed that the catheter does not meet the specified tensile strength requirements.

Given that this device has failed to meet the standard for tensile strength, and that this is not in dispute, the committee was asked if it agreed whether the unique features of this device compensate for the risk of fracture.

The committee discussed the unique feature of the Groshong PICC i.e. it is a closed-end catheter with a slit valve. To enable the valve to function, the Groshong catheter is made of silicone, which is a softer material than other materials such as polyurethane. Silicone catheters are likely to be less traumatic on insertion and have a possibly lower risk of thrombosis. The potential disadvantage of silicone catheters is that the softer material risked fracture or rupture at points where the catheter bent or kinked (e.g. at the bending elbow or shoulder points). Little information was available on the types of fractures reported for the Groshong PICC, and so it was difficult to determine the risk of fracture of this device.

The committee discussed the relevance of the tensile strength test. The clinical significance of the difference between breakage under 10 N force (as required by the

relevant standard) and 7.5 N (as determined for the Groshong PICC) was unclear. There was no evidence about the relationship, if any, between the tensile strength test and the risk of in vivo breakage or fracture of a PICC.

The committee advised that the Instructions for Use (IFU) for the Groshong PICC appeared sufficiently detailed, with warnings on the possibility of catheter breakage and information on patient selection. The committee noted that Safety Alerts issued by the TGA in 2008[2] had led the TGA to identify opportunities for improvements to the label warnings and IFU accompanying all PICC devices. On balance the committee agreed that the low (7.5 N) tensile strength alone does not indicate that any corrective action is necessary.

Toxic Anterior Segment Syndrome (TASS) – Alcon ophthalmic devices

The TGA noted an increase in the number of reports for TASS, including clusters of TASS e.g for patients undergoing the same procedure on the same day. In addition to the information presented in the agenda papers, the committee referred to the very recent publication by The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) titled 'Guidelines on Toxic Anterior Segment Syndrome'[3].

The committee was asked if it could suggest any further investigation by the TGA regarding the event of TASS. The committee noted the TGA comment that the IRIS data had not established a direct association of TASS with individual devices.

The committee also noted that the evidence implicating Alcon devices did not appear strong. The reported clusters seemed more likely to be site-specific (e.g. a likely association with cleaning technique and sterilisation practices for re-usable instruments) rather than device-specific, but again there was no evidence to verify this. Overall, the committee agreed that no further investigation was warranted by TGA at this time.

Given the recent work undertaken by the RANZCO, the committee supported liaison and information sharing between the TGA and the RANZCO regarding reports of TASS. This could include how to determine when a device was implicated in a case, thresholds for defining clusters/outbreaks, data collection, and review to identify different covariates when cases arise, etc.

Post-market monitoring

At this meeting, the committee's advice was also sought on the need for post-market monitoring of the Maestro Neuroregulator and a possible association between breast implants and Anaplastic Large Cell Lymphoma (ALCL).

Maestro Neuroregulator

The committee noted that the mandatory three years of annual reporting required for this type of medical device concluded in 2014. However, nil devices have been supplied during these years, and consequently there are nil reports in the TGA Incident Report Investigation Scheme (IRIS) database. The TGA sought the committee's advice on the need for continued post market monitoring for this novel high risk device.

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[2] TGA website - Peripherally inserted central catheters (PICC lines) (all alerts)
[3] The Royal Australian and New Zealand College of Ophthalmologists. 'Guidelines on Toxic Anterior Segment Syndrome', published 23 March 2015

The committee noted that the US Food and Drug Administration (FDA) has required two post-approval studies and advised that the sponsor should continue to provide annual reports. The sponsor should also be asked to provide the TGA with copies of the Post Approval Study Protocols and regular updates on those studies.

The committee suggested that the TGA may wish to obtain individual patient data on the Australian participants in several published trials in order to ascertain if this information provided any additional details on the safety and performance of the device.

Anaplastic Large Cell Lymphoma and breast implants

The committee noted that in 2011, the US Food and Drug Administration (FDA) released a safety communication to warn about a possible association between breast implants and Anaplastic Large Cell Lymphoma (ALCL). Additionally, two key publications on ALCL and breast implants appeared in early 2015.

Brody et al[4] analysed 173 cases of ALCL in women with breast implants, including published studies and unreported cases and follow-up with authors and physicians. While this is the most comprehensive review to date, the review is incomplete (e.g. information on markers to identify the stage of lymphoma proliferation is incomplete). Separately, the French National Institute of Cancer (INCa) held an expert meeting on 4 March 2015 and have published their view that 'in general, the level of evidence available on ALCL associated with a breast implant is low or very low' and that they will continue to monitor this issue.

The committee did not suggest any further investigations or actions apart from the normal monitoring activities undertaken by the TGA. The signal of a relationship between breast implants and ALCL is very, very small, and the committee offered no suggestions on how to further reduce this very small risk. The TGA's current information that ALCL is a very rare complication of breast implants should be maintained. The known complication should be included in Instructions for Use documents and other educational material for surgeons.

An appropriate public health message for patients is that they should promptly seek medical attention if they have any concerns or notice any changes, abnormalities or symptoms develop within the breasts and/or breast implants.

Risk Management Plans

A Risk Management Plan (RMP) is a set of pharmacovigilance activities and interventions designed to identify, characterise and/or manage risks relating to a therapeutic good. No RMPs were considered at this meeting.

Stakeholder engagement

From time to time representatives from other statutory committees and international regulators are invited to attend a TGA statutory advisory committee meeting.

[4] Brody GS, Deapen D, Taylor CR, et al. Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases. Plast Reconstr Surg 2015; 135(3):695-705. doi: 10.1097/PRS.0000000000001033.

In this context, it is a standing arrangement for representatives from New Zealand's Medicines and Medical Devices Safety Authority (MEDSAFE), to participate in ACSMD meetings as observers.

Subcommittee update – Orthopaedic Subcommittee (OSC)

The ACSMD also considered a report from the two most recent (5th and 6th) meetings of its Orthopaedic Subcommittee (OSC).

The OSC's functions are to advise the ACSMD and the TGA on prostheses which have been identified in the Australian Orthopaedic Association's National Joint Replacement Registry (AOANJRR) Annual Report as having a higher than expected revision rate. This includes:

- assessment of clinical data and other relevant information (including submissions from the sponsor) and provision of advice on whether the revision rates associated with the joint replacement are acceptable;
- consideration of possible reasons for the higher than expected rates of early revision for the identified implants, including if there is a link between implant design or manufacture and the revision rates; and
- providing advice on the strength of the evidence to support the benefit of joint replacement compared with the higher risk of a possible early revision.

The OSC also provides the TGA with advice in relation to orthopaedic issues in general.

The OSC generally convenes three (3) times per year and each new 'review cycle' commences following publication of the latest AOANJRR Annual Report in October each year. Once that report is released, the OSC then usually meets in December each year to firstly consider those orthopaedic implants that have been 'newly identified' in that year's AOANJRR Annual Report as having higher than expected rates of revision.

The second meeting is then usually held in March the following year and gives further consideration to some of the 'newly identified' implants which were first considered at the previous December meeting. These are generally implants for which sufficient concern was initially raised by the OSC at its December meeting to warrant further consideration of the most recently available AOANJRR data, rather than waiting for a full 12 month period to elapse before further review occurs.

The third yearly OSC meeting is usually held two months later, in May, to give further consideration to orthopaedic implants (and / or implant combinations) which are still used and have been "re-identified" in the AOANJRR Annual Report as having higher than expected revision rates. The implants considered at this meeting have already been identified in one or more of the earlier AOANJRR Annual Reports and previously referred to the OSC (and its predecessor) for advice (and the advice at those previous meetings, was that the TGA should 'continue to observe' these implants and 'revisit them at a future meeting if necessary').

When the OSC advises the TGA to 'continue to observe' an implant, this implies that the OSC's view is that the TGA should not be considering regulatory action in relation to the product at that time. However, such advice does not infer any definitive committee view as to the current safety and performance of that device.

OSC Meeting 5

The 5th meeting was held on 8 December 2014. There were 15 'newly identified' implants / implant combinations considered at this meeting and the OSC's advice to the TGA is tabulated below.

Implant / Implant Combination	Sponsor	OSC advice / outcomes
Unipolar Modular Hip Prosthesis: Femoral Head (JRI) Unipolar Modular Femoral Head when used with the Furlong LOL Femoral Stem	Orthotech Pty Ltd	The OSC advised that the revision rate should continue to be observed by the TGA and that the product could be revisited at a future OSC meeting if necessary. The sponsor/manufacturer should be approached to contraindicate or warn against the use of this Unipolar Modular Femoral Head with uncemented femoral stems in the Instructions for Use, the surgical guide, and any other supporting materials provided with the implant.
Bipolar Hip Prosthesis: Synergy Femoral Component when used with the Bipolar Femoral Heads	Smith & Nephew	The OSC advised that the revision rate should continue to be observed by the TGA and that the product could be revisited at a future OSC meeting if necessary. The sponsor/manufacturer should be approached to contraindicate or warn against the use of this Unipolar Modular Femoral Head with uncemented femoral stems in the Instructions for Use, the surgical guide, and any other supporting materials provided with the implant.
Total Conventional Hip Prosthesis: Corail (Depuy) Femoral Component when used with the Trabecular Metal Shell (Zimmer)	Depuy/Zimmer	The OSC advised that the revision rate should continue to be observed by the TGA and that the products could be revisited at a future OSC meeting if necessary.
Total Conventional Hip Prosthesis: CPT Femoral Component when used with the Fitmore Acetabular Component	Zimmer	The OSC advised that the revision rate should continue to be observed by the TGA and that the product could be revisited at a future OSC meeting if necessary.

Implant / Implant Combination	Sponsor	OSC advice / outcomes
Total Conventional Hip Prosthesis: Taperloc Femoral Component when used with the M2a Acetabular Component	Biomet Australia Pty Ltd	The revision rate was high and there was sufficient evidence to indicate that the performance and safety of the combination, a metal on metal hip implant, was unacceptable. The committee also advised that the use of the M2a acetabular component does not offer benefits that compensate for the higher risk of revision and the TGA should consider what 'regulatory action'[5] was possible and necessary to reduce the additional risk of revision. The OSC advised that the revision rate of the Taperloc Femoral Component should continue to be observed by the TGA and that the product could be revisited at a future OSC meeting if necessary. Note: in 2011 the sponsor ceased supplying the M2a products identified in the 2014 AOANJRR Annual Report for metal-on-metal use. In early 2015, the sponsor agreed to cancel the relevant products from the Australian Register of Therapeutic Goods and issue a Hazard Alert to specified surgeons. Further details of these actions are available at - https://www.tga.gov.au/cancellations-requested-sponsor-certain-devices-within-entry and https://www.tga.gov.au/alert/biomet-m2a-metal-metal-total-hip-replacement-implants
Total Conventional Hip Prosthesis: Emperion Femoral Component	Smith & Nephew	The revision rate should continue to be observed by the TGA and that the product could be revisited at a future OSC meeting if necessary.

[5] 'Regulatory action' by the TGA involves one or more of a wide range of actions which can include working with the product sponsor to improve product labelling, amending details within the Instructions for Use or Surgical Technique documents and improvement to education and training material for both healthcare professionals and patients. Regulatory action can also include the publication of Safety Advisories / Alerts, recall actions and the cancellation of products from the Australian Register of Therapeutic Goods (ARTG). All Safety Advisories / Alerts, Recall actions and ARTG cancellations are published on the following pages of the TGA website - https://www.tga.gov.au/safety-information and https://www.tga.gov.au/cancellations.

Implant / Implant Combination	Sponsor	OSC advice / outcomes
Total Conventional Hip Prosthesis: Deltalox Acetabular Component	RQ Solutions	The revision rate of the DeltaLox Acetabular Component was high, notwithstanding its use with a range of femoral stems that were also associated with high revision rates. There was sufficient evidence to indicate that the performance and safety of the implant was unacceptable. The committee also advised that the use of the DeltaLox Acetabular Component does not offer benefits that compensate for the higher risk of revision and the TGA should consider what regulatory action was possible and necessary to reduce the additional risk of revision.
Total Knee Prosthesis: Genesis II CR (Cementless) Femoral Component when used with the Profix Mobile Tibial Component	Smith & Nephew	The revision rate was high, and there was sufficient evidence to indicate that the performance and safety of the combination was unacceptable and that it is the performance of the Profix Tibial component that is of concern and the cause of the increasing revision rate observed with this combination. The committee also advised that use of the implant combination does not offer benefits that compensate for the higher risk of revision and that the TGA should consider what regulatory action was possible and necessary with respect of the Profix Mobile Tibial Component to reduce the additional risk of revision. However, the OSC advised that the revision rate of the Genesis II CR (Cementless) Femoral Component used in other combinations should continue to be observed by the TGA and that the product could be revisited at a future OSC meeting if necessary.
Total Knee Prosthesis: GMK Primary (Cementless) Femoral Component when used with the GMK Primary Tibial Component	Medacta Australia Pty Ltd	The TGA should obtain fresh data from the AOANJRR that includes information up to the end of 2014 about the revision rate. The OSC agreed to further consider this implant combination at its next meeting in March 2015.

Implant / Implant Combination	Sponsor	OSC advice / outcomes
Total Knee Prosthesis: Optetrak-CR (Cemented) Femoral Component when used with the Optetrak (Cemented) Tibial Component	Exactech	Observing the fact that quite a few Optetrak implant combinations have now been identified as having a higher than expected rate of revision, the TGA should investigate the Optetrak range of knee implants very closely. The TGA should raise the concerns with the sponsor/manufacturer regarding the rate of revision and investigate what can be done to reduce the risk of revision associated with the use of this combination of devices. The TGA may also wish to seek additional information from the registries in New Zealand, UK and Italy on the use of these implants. The OSC agreed to further consider this implant combination at a future meeting at the conclusion of the TGA's investigation.
Total Knee Prosthesis: Scorpio NRG PS (Cementless) Femoral Component when used with the Series 7000 (Cementless) Tibial Component	Stryker Australia Pty Ltd	The TGA should obtain fresh data from the AOANJRR that includes information up to the end of 2014 about the revision rate. The TGA should also obtain fresh data from the AOANJRR that includes information up to the end of 2014 about the revision rate of the cemented variants of the Scorpio Femoral Component, for comparison. The OSC agreed to further consider this implant combination at its next meeting in March 2015.
Total Knee Prosthesis: Vanguard PS Femoral Component when used with the Maxim Tibial Component	Biomet Australia Pty Ltd	The TGA should obtain fresh data from the AOANJRR that includes information up to the end of 2014 about the revision rate. This should include a subgroup analysis including reasons for revision of the performance of the Maxim Tibial Component in the catalogue range 141251-141257, and the Vanguard PS Femoral Component in the catalogue range 183100-183136. The OSC agreed to further consider this implant combination at its next meeting in March 2015.

Implant / Implant Combination	Sponsor	OSC advice / outcomes
Total Knee Prosthesis: LCS PS Femoral Component	Depuy	The revision rate was high, and there was sufficient evidence to indicate that the performance and safety of the component was unacceptable. The committee also advised that use of the implant did not offer benefits that compensate for the higher risk of revision and that the TGA should consider what regulatory action was possible and necessary to reduce the additional risk of revision.
Total Conventional Shoulder Prosthesis: Vaios Humeral Stem when used with the Vaios Glenoid Component	Orthotech Pty Ltd	The TGA should obtain fresh data from the AOANJRR that includes information up to the end of 2014 about the revision rate. The TGA should also identify what professional education material had been distributed relating to the use of these devices. The OSC agreed to further consider this implant combination at its next meeting in March 2015.
Total Conventional Shoulder Prosthesis: Comprehensive Humeral Stem when used with the Comprehensive Glenoid Component	Biomet Australia Pty Ltd	The TGA should obtain fresh data from the AOANJRR that includes information up to the end of 2014 about the revision rate. The OSC agreed to further consider this implant combination at its next meeting in March 2015.
Consideration of a "re-identified" implant / implant combination		
Metha femoral stem for total hip replacement	B Braun Australia Pty Ltd	The revision rate should continue to be observed by the TGA and that the product could be revisited at a future OSC meeting if necessary.

OSC Meeting 6

The 6th meeting of the OSC was held on 31 March 2015 and gave further consideration to five (5) "newly identified" implants / implant combinations which were first considered during OSC 5 following their identification for the first time in the 2014 AOANJRR Annual Report as having higher than expected revision rates. The OSC's advice to the TGA is tabulated below.

Implant / Implant Combination	Sponsor	OSC advice / outcomes
Total Knee Prosthesis: GMK Primary (Cementless) Femoral Component when used with the GMK Primary (Cementless) Tibial Component	Medacta Australia Pty Ltd	The OSC remained concerned about the high rate of revision and that the use of the implant combination did not offer benefits that compensate for the higher risk of revision. The TGA should raise the concerns with the sponsor regarding the numbers and types of revisions (including the numbers of major revisions) and investigate what can be done to reduce the risk of revision associated with the use of the implant.
Total Knee Prosthesis: Scorpio NRG PS (Cementless) Femoral Component when used with the Series 7000 (Cementless) Tibial Component	Stryker Australia Pty Ltd	The revision rate remains unacceptably high, and there is sufficient evidence to indicate that the performance and safety of the device are unacceptable. The TGA should consider what regulatory action is possible and necessary to reduce the additional risk of revision, such as recommending that cementless fixation not be used.
Total Knee Prosthesis: Vanguard PS Femoral Component when used with the Maxim Tibial Component	Biomet Australia Pty Ltd	The revision rate should continue to be observed. The devices could be revisited at a future OSC meeting if necessary.
Total Conventional Shoulder Prosthesis: Vaios Humeral Stem when used with the Vaios Glenoid Component	Orthotech Pty Ltd	The revision rate remains unacceptably high, and there is sufficient evidence to indicate that the performance and safety of the device is unacceptable. The committee also advised that use of the implant does not offer benefits that compensate for the higher risk of revision and that the TGA should consider what regulatory action is possible and necessary to reduce the additional risk of revision.
Total Conventional Shoulder Prosthesis: Comprehensive Humeral Stem when used with the Comprehensive Glenoid Component	Biomet Australia Pty Ltd	The revision rate appeared to be improving. The committee advised that the revision rate should continue to be observed by the TGA and that the devices could be revisited at a future OSC meeting if necessary.

The OSC also provided advice in relation to an application for the transition of several orthopaedic implants from Class IIb to Class III in the ARTG.

The outcomes of these OSC meetings were noted by the ACSMD. The subcommittee's advice is now being considered as part of the TGA's regulatory decision making processes.

OSC Meetings 7 and 8

The 7th and 8th meetings of the OSC were held on 26 May and 21 July 2015 respectively. The outcomes of those meetings will be reported to the next ACSMD meeting which is scheduled to be held on 26 August 2015.

The next meeting of the OSC is scheduled to be held on 7 December 2015.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACSMD, please visit the ACSMD webpage or contact the ACSMD Secretary, Mr Craig Davies on 02 6232 8641 (telephone) or via email: acsmd.secretariat@tga.gov.au