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EDITORIAL

# Council of Australian Therapeutic Advisory Groups: supporting the Quality Use of Medicines across the acute-care sector

For Australian health consumers, access to safe, effective and affordable medicines that are prescribed and administered for optimal patient outcomes is fundamental to our standard of healthcare. To this end, Australia has an established National Medicines Policy[1] in which the Quality Use of Medicines (QUM) is a central tenet. In 1998, the Australian Department of Health and Ageing commenced funding an independent organisation, the NPS MedicineWise, to improve the QUM in our community. However, at a jurisdictional level, Therapeutic Advisory Groups (TAG, or their equivalent) have also been established in each Australian state and territory in response to the National Medicines Policy and to address the approximately 15% of adverse events in hospitals that are due to adverse drug events.[2–4] These TAG are diverse in name, structure and accountability, but consistently aim to provide independent expert advice regarding the QUM within the acute-care sector under their jurisdiction. The common purpose of each TAG is to address the key therapeutic and medicines governance issues faced by hospitals and to provide policy and guidance relating to medication use, safety, access and cost-effectiveness to the health systems they support.

After several years of informal collaboration, the state and territory TAG formally established the Council of Australian Therapeutic Advisory Groups (CATAG) in 2008 as a consensus-based collaboration of representatives from each state and territory TAG. CATAG was established with the aim of standardising and improving the use of medicines in Australian hospital practice and across transitions of care through information sharing, advice and advocacy activities. The ability of CATAG members to share, discuss, influence and act upon therapeutic issues which cascades through jurisdictional TAG to the hospital level and local drug and therapeutics committees allows for a national approach and greater consistency to medicines governance and therapeutic decision-making processes across Australia.

All state TAG have area-wide policies for the use of medications in their hospitals. It was apparent that many of these policies could be improved with input from other state TAG and then could be adapted nationally so that there was harmonisation across the country. By consulting with CATAG members and their constituents, CATAG has developed the following national guidelines for medication use which we wish to bring to the attention of the wider medical community. The polices have been developed using evidence where available and then obtaining consensus across all TAG members that make up CATAG.

Two of the recently released guidelines are briefly described below. The development process is evolving. Recent examples, such as the off-label medicines use guidance, have followed a more rigorous process, with national leadership, engagement of a range of specialised therapeutics/QUM and clinical expertise in the development team and wider consultation with relevant national organisations and clinician networks. A more detailed description of this process is available in Appendix 1 at http://www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf.

All of the following can be downloaded from the CATAG website at http://www.catag.org.au:

- Achieving effective medicines governance: guiding principles for the roles and responsibilities of drug and therapeutics committees in Australian public hospitals
- Rethinking medicines decision-making in Australian hospitals: guiding principles for the quality of off-label medicines
- Managing medicines access programmes in Australian hospitals
- Overseeing the use of biosimilars in Australian hospitals
- Guiding principles for the use of complementary and alternative medicines in Australian public hospitals
- Guiding principles for managing use of medication samples in Australian hospitals.

## Achieving effective medicines governance: guiding principles for the roles and responsibilities of drug and therapeutics committees in Australian public hospitals

Drug and therapeutics committees (DTC) operate within the acute care sector nationally to varying degrees and are responsible for local medicines management within state/territories, local health districts/networks or at an individual hospital level. All are grappling with

medicines decision-making and the oversight of medicines management within their area of responsibility. Reports from individual state TAG members were that DTC at the local level varied in the roles that they played at each institution. In 2013, CATAG conducted a national survey of DTC across Australia. The survey confirmed this variation and supported the prioritisation and development by CATAG of guidelines on the role, operation and evaluation of DTC within Australian public hospitals. The intent of the guiding principles for DTC is to facilitate sound, consistent and standardised decision-making and oversight of medicines management. Anecdotally, the guiding principles for DTC have been welcomed by hospitals to assist them in meeting the National Safety and Quality Health Service Standards (Standard 4: medication safety). The impact of the guiding principles for DTC will be assessed through a follow-up survey of DTC towards the end of 2014.

## Rethinking medicines decision-making in Australian hospitals: guiding principles for the quality use of off-label medicines

Off-label use of medicines is a common therapeutic approach for many clinicians and patients in Australia, particularly in specialised care settings. Clinical, safety, ethical, legal and financial considerations require that there is a careful and responsible approach to the off-label use of medicines to ensure the QUM applies in these situations. The purpose of the off-label guiding principles is to provide a framework to support the quality use of off-label medicines in Australian public hospitals. These principles are intended to assist decision-making by health professionals, consumers and DTC in the evaluation, approval and use of these medicines. This work provides an important update on previously available Australian guidance, addressing a complex topic which is the subject of ongoing controversy.[5,6] Since its release in late 2013, the framework has been presented widely at national professional and scientific meetings, as part of a systematic dissemination strategy. Priority areas of further work have been identified to support optimal implementation (see Appendix 2 at http://www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf).

As well as sharing of information and data between the various state TAG, CATAG has actively sought an advocacy role in medication safety with the Australian Commission on Safety and Quality in Health Care and consults regularly with the Therapeutic Goods Administration, Medicines Australia, the National Medicines Policy Committee, Pharmaceutical Benefits Advisory Committee, Society of Hospital Pharmacists of Australia, Independent Hospital Pricing Authority and NPS MedicineWise which supports CATAG's operations. We have representatives on a variety of national committees, including the Australian Commission on Safety and Quality in Health Care's Antimicrobial Stewardship Committee, Medication Reference Group and the Health System Medication Expert Advisory Group. CATAG provides a nomination to the Department of Health and Ageing's Drug Utilisation Sub-committee.

CATAG assists with the development of national Drug Use Evaluation projects and carried out a survey examining the off-label use of rituximab in Australian public hospitals which was recently published.[7] It has provided several submissions and presentations to national forums on the use of medications in hospital practice. Currently, CATAG is finalising a policy statement on the use of biosimilars in public hospitals.

CATAG also has several aspirational goals:

- Equity of access across all Australian hospitals – no longer is it acceptable for some hospitals and hospital patients to have access to some high-cost medications while others do not
- Independent pharmaco-economic capabilities to assess high-cost medications that are either never reviewed or are rejected by the Pharmaceutical Benefits Advisory Committee for use in the general community under the Pharmaceutical Benefits Scheme, but where these medicines have a potential role in hospital and specialty practice
- A national scheme to evaluate the use of all off-label, high-cost medications used in Australian hospitals. We require a method and the resources to collect the clinical outcomes learnt from our use with these medications to inform future practice better.

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REVIEW

# Management of systemic AL amyloidosis: recommendations of the Myeloma Foundation of Australia Medical and Scientific Advisory Group


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## Abstract

Systemic AL amyloidosis is a plasma cell dyscrasia with a characteristic clinical phenotype caused by multi-organ deposition of an amyloidogenic monoclonal protein. This condition poses a unique management challenge due to the complexity of the clinical presentation and the narrow therapeutic window of available therapies. Improved appreciation of the need for risk stratification, standardised use of sensitive laboratory testing for monitoring disease response, vigilant supportive care and the availability of newer agents with more favourable toxicity profiles have contributed to the improvement in treatment-related mortality and overall survival seen over the past decade. Nonetheless, with respect to the optimal management approach, there is a paucity of high-level clinical evidence due to the rarity of the disease, and enrolment in clinical trials is still the preferred approach where available. This review will summarise the Clinical Practice Guidelines on the Management of Systemic Light Chain (AL) Amyloidosis recently prepared by the Medical Scientific Advisory Group of the Myeloma Foundation of Australia. It is hoped that these guidelines will assist clinicians in better understanding and optimising the management of this difficult disease.