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## Palliative Care Clinical Studies Collaborative PaCCSC

### **Background**

Supporting access to appropriate medicines to help maintain comfort and function during the terminal phase of a person's life when people are being cared for at home is one focus of the Australian Government's National Palliative Care Program. Through the Palliative Care Medicines Working Group (PCMWG) increased access to palliative care medicines in the community under the Pharmaceutical Benefits Scheme (PBS) has been achieved with the implementation and ongoing development of the palliative care section under the PBS.

The medicines listed on the Pharmaceutical Benefits for Palliative Care allow a greater number of palliative care patients to access their medicines in the community at a more affordable cost.

Initial work on medicines considered to be essential for good palliative care was completed in 2003. Minor submissions to support cost minimisation or clinical superiority in palliative care were prepared for medications registered for the relevant formulation, palliative indication and route of administration for consideration by the PBAC.

Since 2003, additional medicines have been identified using the initial framework of the Palliative Care Medicines Working Group to progress for listing on the Pharmaceutical Benefits for Palliative Care. A number of these priority medications have not been assessed by the Therapeutic Goods Administration (TGA) for the palliative indications sought.

In developing the essential medication list for palliative care, the palliative care section for the PBS and PaCCSC, the PCMWG has embraced the four central objectives of the Australian National Medicines Policy:

- Timely access to and affordable cost of medicines
- Appropriate standards of quality, safety, efficacy
- Quality use of medicines
- Maintaining a responsible and viable medicines industry.

The Australian work of the PCMWG was recently acknowledged internationally as part of the WHO process for establishing an essential medicines list as having achieved a framework that provides a model for other countries.

The *Palliative Care Medications Scoping & Research Study* systematically reviewed the available evidence and worked with individual sponsor pharmaceutical companies to support changes to the registered indication for a list of priority medications. This project and the initial work was undertaken by a research group from Flinders University and DATIS (Drug and Therapeutics Information Service) under the direction of Professor David Currow.

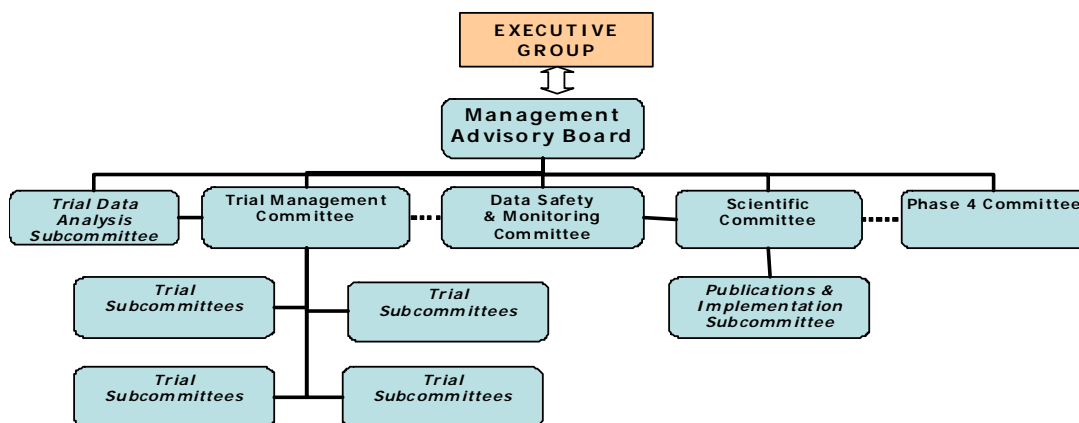
It was anticipated that for some medicines under consideration by the PCMWG, additional evidence would be necessary to support the registration for listing in the palliative care section. For example, megestrol acetate in the management of anorexia or weight loss, and risperidone in the management of delirium for palliative care patients.

The Department of Health and Ageing requested advice on the research infrastructure needed to support the continued development of the evidence base for clinical trials in palliative care. Initially the model was required to support a clinical research agenda to facilitate the registration of new indications, formulations, or routes of administration for medicines with the TGA, as well as data generally developed through rigorous and high quality prospective clinical studies for PBAC submissions.

To examine and ensure the feasibility of the proposed multi-site collaborative model, a workshop was convened which brought together an experienced multidisciplinary group of palliative care researchers. Potential study proposals and key sites to conduct the initial phase of research were discussed. As a result of this work the Palliative Care Clinical Studies Collaborative (PaCCSC) was developed.

### **Palliative Care Clinical Studies Collaborative**

The Palliative Care Clinical Studies Collaborative (PaCCSC) is a research infrastructure that consists of a coordinating agency, a supportive committee structure including a Management Advisory Board (Figure 1) and a number of partner organisations/agencies that will be collaboratively involved in the a number of Phase 3 and Phase 4 clinical medication studies.



*Figure 1: Governance Structure of PaCCSC*

Phase 3 clinical studies will verify the effectiveness of individual medications in symptom management for palliative care patients, and the phase 4 (or pharmacovigilance studies) will provide additional data on the benefit to risk balance for individual medications including the use of medications in normal clinical settings and in comparison with current practice.

These studies may support the registration of medicines used in palliative care on the Australian Register of Therapeutic Goods (ARTG) and subsequently support the listing of these medicines on the Pharmaceutical Benefits Scheme (PBS).

The aims of PaCCSC are to:

- Develop an efficient and effective method of generating research data that will support the listing of palliative care medicines on the ARTG
- To build the research capacity of the palliative care sector so that ongoing clinical medication studies can occur
- To build the evidence base to support the ongoing implementation of studies on medicine use and quality practice in palliative care

## **Partner organisations**

There are currently six Phase 3 partner organisations/agencies associated with PaCCSC.

These organisations/agencies are:

- WA Centre for Cancer & Palliative Care, Western Australia
- Peter MacCallum Cancer Institute, Victoria
- Sydney Cancer Centre, New South Wales
- Liverpool Palliative Care Services, New South Wales
- School of Nursing/CPCRE QUT & Mater Health, Queensland
- Southern Adelaide Palliative Services & Flinders University, South Australia

In addition there are 4 Phase 4 partner organisations/agencies associated with PaCCSC.

These organisations/agencies are:

- Central Adelaide, South Australia
- Launceston, Tasmania
- North Sydney, New South Wales
- Nambour, Queensland

Conducting a number of parallel studies across a number of organisations/agencies through PaCCSC will ensure effective and efficient recruitment of patients and will build research capacity within the palliative care sector.

Expected outcomes of PaCCSC include:

- At least 4 completed Phase 3 clinical medication studies with at least one other Phase 3 study developed to full protocol
- Completed phase 4 clinical medication studies examining current palliative care practice for key symptoms of interest
- A pharmacovigilance study on the prescribing of benzodiazepines in the palliative care population
- Drug utilisation research on medicines with dual listing in the Schedule of Pharmaceutical Benefits
- Data to support submissions to the Therapeutic Drugs Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC)
- Evidence to support the clinical usage of medicines in palliative care
- Increased investigator capacity within the palliative care research community to undertake multi-site clinical medication studies in palliative care
- A pharmaceutical industry aware of the needs of the community for palliative care medicines and responsive to the requirements of the Australian Government to the registration of medicines for a palliative care indication.