

Welcome to the second Palliative Care Medicines Working Group newsletter. Happy New Year to all.

## News from the National Palliative Care Program

### New listings on the PBS

Many of you will be pleased to note that Methadone Hydrochloride oral liquid has been listed in the palliative care section of the Pharmaceutical Benefits Scheme (PBS).

### PBS on-line

PBS on-line is now available to all at [www.pbs.gov.au](http://www.pbs.gov.au). We urge you all to go in, have a look at this new on-line system and let others know about it. If people are having trouble finding medicines listed for a palliative care indication, including those medicines not currently in the dedicated palliative care section, they should provide feedback to the PharmBiz project team. The feedback sheet is available on-line.

It would also be useful that feedback provided to the PharmBiz project team be copied [palliativecare@health.gov.au](mailto:palliativecare@health.gov.au). Then your concerns can be incorporated into the work of the Palliative Care Medicines Working Group (PCMWG) communications sub-group.

### Palliative Care Clinical Studies Collaborative

In June 2006 the Australian Government provided seed funding to support the development of the Palliative Care Clinical Studies Collaborative (PaCCSC). This network of experts consists of researchers from around Australia who have joined forces to facilitate the generation of the scientific evidence to support the listing of medicines on the PBS.

As you are all aware, many of the medicines currently used within the hospital setting are not registered by the Therapeutic Goods Administration (TGA) for a palliative care indication, so can not be listed on the PBS.

In October, Dr Sue Whicker, from Flinders University, South Australia, was appointed the director of the PaCCSC.

The organisations involved in PaCCSC include:

- Department of Palliative and Supportive Services, Flinders University
- Peter MacCallum Cancer Institute
- Sydney Cancer Centre
- WA Centre for Cancer and Palliative Care
- Centre for Palliative Care Research and Education / Queensland University of Technology / Mater Health Services Queensland

- Liverpool Palliative Care Services
- Royal Prince Alfred Hospital, Sydney.

## Funds available to support palliative care medicine communication and awareness activities

Just to remind you all that there are funds available to support the work of the palliative care medicines communication network. If anyone would like to present material on palliative care medicines at a conference or workshop, we are happy to support you. Please send any funding application by email to [palliativecare@health.gov.au](mailto:palliativecare@health.gov.au).

The Department has already provided funds to support medicines workshops in rural Victoria and South Australia.

## Resources available

If you would like any resources — bookmarks, fact sheets, posters or the August edition of the PBS Schedule, please email [palliativecare@health.gov.au](mailto:palliativecare@health.gov.au).

Further information about the initiatives and palliative care publications funded under the Australian Government's National Palliative Care Program can be found on our website – <http://www.health.gov.au/palliativecare>.

## Feedback from the states

We have had some feedback from Nancy Cutlack and Odette Spruyt following their presentations to general practitioners, nurses and pharmacists in the Loddon Mallee region of Victoria.

The following questions were posed during the sessions. They deal mainly with the palliative care section that is contained within the Schedule of Pharmaceutical Benefits. It may be useful for you to hear how the experts on the PCMWG would have responded to these questions.

### **What is the definition of a palliative patient?**

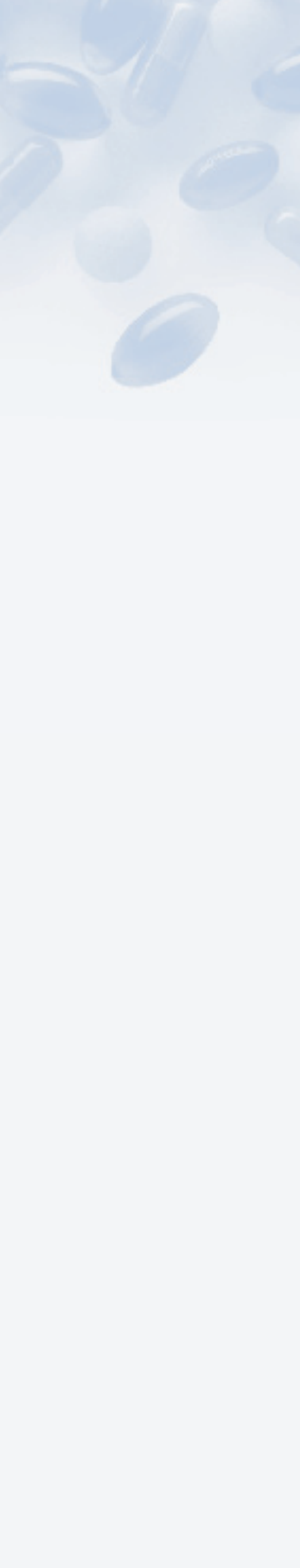
For the purposes of the PBS, the Pharmaceutical Benefits Advisory Committee (PBAC), on advice from the PCMWG, adopted the Oxford Textbook of Palliative Medicine's definition of palliative care. According to this definition, palliative patients are ...

patients with active, progressive, far advanced disease for whom the prognosis is limited and the focus of care is the quality of life.

This definition is broad enough to include all patients with a far advanced progressive disease, not just those people with cancer.

### **Why is the length of authority four months, rather than six months as for opioids?**

Four months was chosen as the initial authority period as research has shown that most palliative care patients die within this period.



Where continuing treatment is required, there is provision for repeats following consultation between the prescribing doctor and a palliative care physician or palliative care service regarding the care of the patient. The patients themselves do not have to be seen by a palliative care service or palliative care specialist – a telephone consultation between the patient's general practitioner and a palliative care specialist or service is sufficient.

If a consultation does not occur, then authority to prescribe is limited to one month per approval.

This approach was considered the most appropriate in the initial phase of the establishment of the palliative care section to ensure the ongoing support of palliative care patients. The process continues to be reviewed by the PCMWG and will be discussed at a future meeting.

### **What is the likely success of the efforts to obtain acceptable evidence to achieve TGA registration and/or PBS listing of other medications identified as essential?**

The establishment of the PaCCSC provides the opportunity to systematically examine and gather the evidence base to support the use of medicines in palliation, and to understand where there are gaps in the evidence.

Every effort has been made to ensure that the methodology and the research questions that will be evaluated will generate the evidence required to satisfy the rigorous requirements of TGA and the PBAC.

The collaborative nature of this research group will ensure that the data required will be collected in the most efficient and effective way. Also, there are ongoing discussions with pharmaceutical companies to encourage them to consider the potential palliative care application for new and current medicines registered on the Australian Register of Therapeutic Goods.


### **Why is the Australian Government taking its current approach rather than supplying funds to hospital so that they can supply essential medicines to community patients?**

Providing funds to hospitals so that they can supply essential medicines to the community including palliative care patients is one approach which the Australian Government already uses. An example would be Section 100 medicines.

But the approach of listing medicines in a palliative care section in the Schedule of Pharmaceutical Benefits is intended to address the long term need of providing access to a broader range of palliative care medicines to patients in the community setting by allowing additional subsidised medicines to be available.

The goal is to improve equity of access and increase the ability of all clinicians to improve the provision of palliation in the place of their patient's choice.

As the number of palliative care patients in the community increases, the need to have medicines used in palliation listed through the PBS is increasingly seen as important.



The approach adopted by the Australian Government will not only build the evidence to support the use of medicines in palliation, but will also increase the capacity of the palliative care research community and demonstrate to pharmaceutical companies that research in palliative care can occur. This approach will provide both GPs and palliative care specialists with the evidence base for selected medicines with regard to efficacy, effectiveness and the potential for harm.

It may be of interest to note that a recent study from Peter MacCallum Cancer Centre in Melbourne demonstrated that about 22% of all medicines prescribed in palliative care were prescribed “off label” (Poole and Dooley, 2004).

Further to this, Fonzo-Christie et al (2005) found that only 38% of palliative care medicines administered subcutaneously to the elderly were licensed for this route of administration.

### Article in Australian Doctor

Dr Geoff Mitchell had a 5000 word article published on palliative care in the home in the 22 September 2006 edition of Australian Doctor.

### Essential Medicines in Palliative Care – International Workshop

The Department of Health and Ageing provided funds to Palliative Care Australia (PCA) to support Debra Rowett’s attendance at the Essential Medicines in Palliative Care workshop in Salzburg, Austria, from April 30 to May 2, 2006.


Thirty-one representatives from 26 organisations involved with pain and palliative care attended.

The Cancer Control Program of the World Health Organisation (WHO) asked the International Association for Hospice and Palliative Care (IAHPC) to convene the workshop to develop a list of drugs considered essential to the palliative care of patients. The list should take into account both effectiveness and safety of the medicines proposed.

Before this workshop, the IAHPC formed a working committee co-chaired by Neil MacDonald (McGill University, Canada) and Carla Ripamonti (National Cancer Institute, Italy). Other members of the committee included Kathleen Foley (chair of the IAHPC) and David Currow (Australia).

The committee focused on symptoms rather than treatment of underlying conditions, and so excluded therapies for cancer, HIV and other infections. Using an evidenced based approach and recent meta-analysis, the committee developed a list of the most common symptoms. They are:

- pain
- dyspnoea
- terminal respiratory congestion
- dry mouth
- hiccups
- anorexia/cachexia
- constipation

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- diarrhoea
  - nausea
  - vomiting
  - fatigue
  - anxiety
  - depression
  - delirium
  - insomnia
  - terminal restlessness
  - sweating.

This committee then contacted a range of palliative physicians around the world, including 15 from developing countries, to propose drugs used to treat these symptoms. This process generated 120 drugs.

The next phase involved a broader range of physicians and pharmacologists, 77 of whom were from developing countries, who were invited to rate the drugs using a modified Delphi process. For each medication, respondents were asked to rate safety and efficacy on a scale of 1– 9 using a set of definitions. This process was used to inform the workshop in Salzburg.

Dr MacDonald opened the workshop in Salzburg with an overview of the process to date and the agenda for the workshop – participants were appraised of the principles to guide their considerations and discussions and of the global approach of the WHO Model List of Essential Medicines (<http://www.hospicecare.com/resources/edl.pdf>).

Suzanne Hill (WHO) gave an excellent presentation on the concept of essential medicines and defined essential medicines as the following.

Essential medicines are those that satisfy the priority health care needs of the population. They are selected on the basis of:


- disease prevalence
- evidence of comparative efficacy, safety and cost-effectiveness.

Dr Hill also outlined the rigorous process for adding a new medicine to the WHO Model List of Essential Medicines which takes into account, among other things:

- public health needs
- phase I, II and III trials
- regulatory processes
- post marketing surveillance
- comparative effectiveness
- safety.

There were a range of invited presentations across the workshop to help inform and share international experiences.

Debra Rowett (PCA) presented the Australian experience particularly with regard to the regulatory processes and the roles of the TGA and PBAC within the Australian National Medicines Policy framework.



The majority of the time at this workshop was spent working in small groups to develop a list of medications which had the highest ranking for each of the symptoms. Each group was assigned a particular set of symptoms. All groups then reconvened and the chairs presented the individual group decisions, which were then debated by the entire assembly until consensus was reached for a medication to be included in the IAHPHC list.

The current IAHPHC list of medicines is available online at <http://www.hospicecare.com/resources/emedicine.htm>

It is important to note that the list of medicines considered essential in palliative care internationally was comparable to the list identified by the Joint Therapeutics Committee of Australian New Zealand Society of Palliative Medicine and the Clinical Oncology Society of Australia in 2001. Most of the drugs addressed by PCMWG are also on these lists.

Feedback from this workshop was extremely positive and the work that is currently being undertaken in Australia was very well received.

## Other international initiatives – the Declaration of Venice

The European Association for Palliative Care (EAPC) and the IAHPHC have also been working on a strategy to develop and promote a global palliative care research initiative, with a special focus on developing countries.

In May 2006, during the Fourth Research Forum of the EAPC in Venice, the EAPC and IAHPHC convened a meeting and joined forces with other regional and academic organisations, including Palliative Care Australia, to initiate this global initiative.

As a result of deliberations and discussions during the meeting, the group adopted and signed what is called the Declaration of Venice, to support the global development of palliative care research.

Organisations hope to use the declaration, with the support of signatories, to call on governments, policymakers, administrators and carers to support palliative care research, especially in developing countries.

You can read about the Declaration of Venice and sign your support at <http://www.hospicecare.com/dv/english.html>.

A list of signatories (currently 25 pages) can be found at [www.hospicecare.com/dv/signed.html](http://www.hospicecare.com/dv/signed.html).

## References

Fonzo-Christie C, Vukasovic C, Wasilewski-Rasca A and Bonnabry P. Subcutaneous administration of drugs in the elderly: survey of practice and systematic literature review. *Palliative Medicine* 2005; 19: 208-219.

Poole SG and Dooley MJ. Off-label prescribing in oncology. *Support Care Cancer* 2004; 12: 302-305.