
# APMA Submission

# to the
# Senate Finance and Public Administration References Committee
# inquiry into
# the Government's administration of the Pharmaceutical Benefits Scheme

## July 2011

## Who we are

APMA is a national consumer health charity which advocates on behalf of the more than 3.2 million Australians from all walks of life estimated to be suffering from persistent (chronic) pain and supports individuals with persistent (chronic) pain, and their families across Australia. The organization is head-quartered in Brisbane, and was established in 2009 in response to the need for evidence-based information and services for people living with persistent pain, and to provide a voice and community support for them, their carers and families.

APMA provides a number of services including:

- a website containing persistent pain information, management options and reliable and accessible information for people living with pain (**www.painmanagement.org.au/** ) ;
- **Pain link**, a national telephone helpline service **1300 340 357**;
- community education and outreach;
- a network of pain support groups;
- lobbying for improved hospital, medical and health services.

As a result of its membership base, services and outreach, APMA deals on a daily basis with the impact of persistent pain, chronic disease and ill-health.

## Introduction

The management of pain in Australia remains shockingly inadequate, despite the efforts of health practitioners, consumer organizations and, belatedly, health authorities. One in five Australians will suffer persistent pain in their lifetime yet up to 80% living with this debilitating condition are missing out on treatment that could improve their health and quality of life. Access Economics in 2007 estimated that persistent pain costs the Australian economy $34 billion per annum, is Australia's third most costly health problem and as the population ages the numbers and costs are only increasing[1]. Despite these figures, persistent pain is still not recognized as a chronic condition for the purpose of action in response to the growing impact on the health of Australians and the health care system[2].

It has been estimated that less than 50% of patients with cancer pain receive effective relief, and similar levels of patients with acute pain fail to receive effective relief – despite the capability of current techniques to relieve more than 90% of such patients. Improved management of acute pain would reduce the subsequent development of chronic pain. It has also been estimated that less than 10% of patients with chronic pain receive effective relief – again, despite the capability of current techniques to relieve more than 80% of such patients, and such relief being capable of reducing the worsening of conditions and symptomology[3].

There are a range of different categories of pain, including acute, chronic, neuropathic and cancer-related pain. Living with and managing persistent pain requires reliable and up-to-date medical treatment (including allied health and pharmaceutical assistance). It also needs self-management

[1] Access Economics Pty Ltd *The High Price of Pain: The economic impact of persistent pain in Australia* MBF Foundation November 2007

[2] National Health Priority Action Council *National Chronic Disease Strategy* Australian Government Department of Health and Ageing, Canberra 2006

[3] National Pain Summit 2010 *National Pain Strategy; Pain management for all Australians* http://www.painaustralia.org.au/images/painaustralia/National_Pain_Strategy_2011.pdf p.2

capability, utilising lifestyle information, activity and support. A combination of these measures can restore function and quality of life to individuals whose main disability is pain.

People living with persistent pain are often poorly served by the pharmaceutical options currently able to be accessed. Opioid-based medications remain contentious, with reducing efficacy over time. Many practitioners experience difficulty prescribing appropriately. There is a reluctance or ignorance on the part of many health practitioners at the primary level when it comes to prescribing appropriate, effective medications[4]. In relation to other pharmaceutical treatments available, numbers needed to treat (NNT) often remain high. Even where medications are available which can provide individual patients with relief and/or assistance, obtaining or affording those medications can be difficult. And many medications which are of assistance are expensive or unaffordable, in many cases because they are not PBS listed or where listed use is restricted to certain indications or conditions only. Many people living with pain are desperate, and often expend considerable sums of money exploring complementary and alternative medicines and therapies with no little or no scientific basis.

It is against this background of a health system inadequately addressing pain and pain management that APMA welcomes the Senate decision to undertake this enquiry. The Pharmaceutical Benefits Scheme is a critical element of a comprehensive, affordable health system for Australian health consumers. It has with reason been lauded as world-leading, and has delivered effective medicines at a cost comparable to any health system in the world. The assessment and basis for determining which medicines, and under what circumstances, should be subsidised by taxpayers, resides with a highly respected independent expert body which is well accepted by industry, clinicians and consumers. That body, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations for listing to the Federal Government taking into account the clinical effectiveness, safety and the cost effectiveness (value for money) of the medication concerned compared to other available therapies.

## APMA's involvement in the PBS assessment process

During its short existence, APMA has sought to provide a viewpoint on behalf of consumers with persistent pain in regard to each application considered by the PBAC which relates to pain relief or management. Each submission is premised on the philosophy that in light of the prevalence and chronicity of persistent pain, the availability of the widest possible range of effective medications at the cheapest price is in the best interest of effective pain management and people with persistent pain. Furthermore, that discrepancies in medication options between consumers arising from ability to pay, and/or differences in access to health funding (through, for example, private health insurance; access to the Repatriation PBS or via workers' or accident compensation schemes) rather than clinical need is unfair and ethically indefensible.

In preparing each submission, APMA emails its members advising them of each pain-related medication listed for discussion at the forthcoming PBAC meeting and their right/ ability and means to make a submission on any matters listed for consideration. APMA seeks succinct advice and information from members about their past or present use, or inability to access, or any other issue a

[4] It is frequently reported that GPs receive less training in pain management than vets. A 1988 report estimated that an average of 3.5 hours in a 5 year medical degree was devoted to pain and pain control (Marcer, D & Deighton, S 'Intractable pain: a neglected area of medical education in the UK' *Journal of the Royal Society of Medicine* Vol 81 Dec 1988). Even if the time devoted to undergraduate training in this area is now (slightly) higher, APMA regularly encounter stories which confirm the need for drastic increases and improvement in the initial and continuing professional development of general practitioners and other primary level allied health practitioners.

member may wish to raise about a medication listed for consideration, in order to inform the APMA submission (identifying personal information is not included). APMA also contacts the members of its Clinical Advisory Committee to seek any input or comments those clinicians might have[5]. We expect that the relevant detailed and economic data regarding each medication will usually have been provided by the sponsor of the product.

## Response to the terms of reference

### *(a) The deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee*

From the first announcement by the Minister for Health and Ageing Nicola Roxon MP on 25 February 2011 of the Government's intention to add a new layer of consideration and delay to each PBAC recommendation to list a medicine on the PBS, APMA has had serious concerns about the implications of the decision. We have sought the reconsideration and reversal of what we described as a "short-sighted economically, as well as cruel and heartless" policy in a letter to the Minister in March. Our concerns are widely shared, and arise not only because of specific medications now deferred indefinitely but in order to avoid the weakening and undermining of an assessment system and arrangements which has served all Australians health consumers (and taxpayers) well.

Whilst it has been standard practice for recommendations for listing costing more than $10 million per year to be considered by Cabinet, recommendations to list have invariably been accepted by the Minister for Health, and once pricing approval from the Pharmaceutical Benefits Pricing Authority has been gained, included on the PBS in a timely manner. This has allowed consumers to purchase the most effective up-to-date medications at affordable prices.

This is no longer the case. A number of medicines recommended for listing by the PBAC at its December 2010 meeting remain in limbo – deferred indefinitely – and only available to a small proportion of 'privileged' patients or those able to afford the much higher cost resulting from the new Government approach. These include Targin - an oral oxycodone/naloxone prolonged-release tablet to control severe chronic pain with significantly reduced risk of opioid-induced constipation. APMA understands that in excess of 50,000 patients per year who would have been expected to access Targin had it been listed in accordance with the PBAC recommendation will now be unable to access the drug. At best those patients will access inferior pain relief – at worst their pain will be unrelieved.

APMA remains concerned that further PBAC recommendations to list medicines on the PBS will be rejected by the Minister every 4 months until at least 2013, notwithstanding the Minister's announcement on 21 June 2011 that no such rejections ('deferrals') resulted from Cabinet's consideration of the positive recommendations to list originating from the March 2011 PBAC meeting. We believe that the unprecedented campaign and opposition from consumers, clinicians, industry – and from within the PBAC – has caused the Government to pause, but not reverse, its new policy approach. Whether this 'pause' continues has yet to become apparent. If it does, it will be welcome but will still leave the December 2010 medicines stranded, unlisted purely as a consequence of the point of time at which they went before Cabinet following PBAC assessment and recommendation.

[5] Details of the membership of APMA's Clinical Advisory Committee can be found at http://painmanagement.org.au/clinical-advisory-committee

APMA believes that the policy to consider and defer the listing of large numbers of medicines assessed and endorsed for listing on the PBS by the PBAC, on a routine basis, will threaten the viability and operations of a well-accepted and critical pillar of the Australian health system. It will inevitably lead to a politicisation of the consideration and assessment of which medicines should gain PBS listing.

It will also compromise the ability of the Government to attract and retain the services of the highly qualified and eminent experts who currently undertake the assessment and analysis, and must over time influence the considerations undertaken by this expert body. Repeated rejections of recommendations by experts, well aware of the sound basis of their recommendations and the degree to which they reflect the intentions of Parliament through adherence to the legislatively mandated assessment criteria, must inevitably lead consciously or unconsciously to changes in how the assessment is undertaken and their conclusions and recommendations are derived. This is even worse if 'second-guessing' of Cabinet's likely position – against unclear criteria – begins to occur (see comments against (e) below). It could also tempt future Governments to appoint less independent experts to avoid having to regularly reject recommendations to list large numbers of medicines.

At the Consumers Health Forum (CHF) convened summit in Canberra on 29 April 2011 the Minister stated that "PBS listings always have the inside running [achieving funding approval compared to competing priorities] because of the strong process they go through with the PBAC but that doesn't mean we must always choose them." APMA does not argue that Cabinet approval or consideration of a recommendation to list a medicine should not occur. But it **does** believe that a Cabinet decision to reject (or 'defer') a listing should not occur lightly and should only rarely be taken. It should not occur without some type of patient impact statement being prepared so that Cabinet (and the patients identified as likely to have accessed the medicine) are aware of the ramifications of not accepting a particular PBAC recommendation.

It would be far preferable to achieve savings or fund alternatives by alternate means – preferably means which are open and transparent and do not threaten the system as a whole. We do not believe this is necessary, for reasons which we believe are clear from this submission, and hence we do not seriously put any such alternatives forward. However, legislative change to the PBAC assessment criteria or eligibility to access subsidized concession benefits are but two alternate options which readily spring to mind as being superior from the perspective of retaining integrity.

***(b) Any consequences for patients of such deferrals***

There are a wide range of consequences for patients (consumers) of these deferrals – some of which are immediate, and some of which will only become apparent over time – for both individual patients and for consumers on a wider basis.

(i) Economic hardship: ill-health, and particularly chronic ill-health, has economic consequences for the individual, their family and society generally. If patients need to use medications which are not listed, and *if they can still afford to use them*, those medications will require a greater expenditure than if listing had proceeded as recommended. Health expenditure, including on medications, is rarely discretionary.

(ii) Health deterioration: if patients cannot afford the non-listed medications, they may cease medications, take the medications on a basis or frequency less than medically recommended,

or utilize inferior (but cheaper) medications. Each of these consequences will have implications for the individual, especially over time. Conditions, and or symptoms, can and will worsen. Consequential medical costs, health outcomes and quality of life/functionality impacts will result.

APMA is particularly concerned at what appears to be a distinction being made between medications which will save lives, and medications which do not (and which are therefore considered to be almost optional). This distinction has become apparent on media coverage of this issue, but has also begun to be identifiable in some public canvassing of the rationale relied upon by Cabinet in deferring certain medications but not others (our comments in relation to (e) below outline the basis for our concerns in this regard). We would strongly argue that such a distinction is misinformed, misleading and superficial.

Chronic diseases – and the suffering associated with such ill-health – are a well-known significant cause of reduced life-expectancy and suicide in our community. Persistent (chronic) pain is a well-recognized cause of mental health problems, and is likely to be the underlying cause of as many as 50% of all suicides in Australia. Clearly medications which relieve or reduce such pain will save lives.

However, even if this were not the case, APMA is of the view that quality of life is just as important as saving life itself. It would be ironic if in the area of palliative care – one of the areas where pain management and medication provision is most efficacious and less concerned about issues such as 'addiction' – dying patients were unable to access the most appropriate pain relief through the PBS because their lives were not going to be saved.

The area of pain, and pain relief, is somewhat unique as it can be a feature of most, if not all, medical conditions. Most consumer health organizations will have an interest in the subject on behalf of the consumers they represent

***(c) Any consequences for the pharmaceutical sector of such deferrals***

Clearly there will be adverse consequences for the pharmaceutical industry as a result of this new Government policy for PBS listing of medicines. Each rejected listing will have financial consequences for the individual company – probably very severe consequences for profitability. It will impact adversely upon the understanding and level of certainty for the industry as a whole, and may very well lead to a reluctance to invest, seek listing or undertake research and development – particularly given the long lead times for development, assessment and listing of pharmaceutical products, and the small size of the Australian market in global terms. It may very well have pricing implications and lead to distortions – a company with a product falling within the new criteria for listing (whatever they are) may seek to gain pricing approval at a higher level than it would have in order to subsidize or compensate for another recommended product which may or may not be accepted by Cabinet.

The pharmaceutical industry/sector will be best placed to provide informed submissions against this term of reference. We are aware of the strong opposition from the sector to the policy – and the disquiet, uncertainty, cutbacks and layoffs which have already occurred.

The potential for flow-on consequences to health consumers is clear. The scale and likelihood is impossible for an organization such as APMA to quantify or even guess at. We are, however, aware of at least one medication which despite past listing has been unable to yet be accessed by Australian

consumers due to insufficient manufacturing capacity unrelated to this new policy), and in relation to which access/availability is now threatened by the uncertainty brought by the new policy.

### *(d) Any impacts on the future availability of medicines in the Australian market due to such deferrals*

Please refer to our comments against (c) above. APMA is not in a position to offer any informed perspective on the potential for the new policy to reduce availability of medicines in the future, but is concerned about the possibility.

### *(e) The criteria and advice used to determine medicines to be deferred*

No criteria for the Cabinet decision were identified by the Minister in her 25 February 2011 announcement, other than "medicines for conditions where existing treatments are already available on the PBS…[6]" On 29 April 2011 in a speech to a Consumers Health Forum (CHF) convened summit in Canberra, the Minister provided no clarification of the criteria applied to Cabinet's drug by drug consideration, merely a vague reference to it "always has been Government's responsibility to decide whether to list a new drug, taking into account other priorities across the health portfolio and fiscal circumstances across government.[7]" In a letter to APMA on the Minister's behalf, coincidently also dated 29 April 2011, the only criterion identified included (but appeared not to be restricted to) "medicines for conditions where existing treatments are already available on the PBS".

However, in a media interview with Alan Jones on 2GB Sydney on 15 June 2011, the Minister (in response to the interviewer's identification that at least one of the deferred medications had no alternative treatment available) characterized the 7 deferred medications as for diseases which "…for some people is quite mild, for others is very severe. It's not life-threatening, not that that is a requirement but we balance up a range of different factors[8]." The criteria were firmer in a subsequent interview, again with Alan Jones on 2GB Sydney on 21 June 2011: "we've prioritised all of those that are life-saving, or where there isn't another treatment available, or where it's a very severe disease[9]."

These putative criteria are vague, variable and, it would appear, highly confidential. In response to direct questioning by Senator Fierravanti-Wells at the Senate Community Affairs Legislation Committee's Estimates hearings on 31 May 2011 as to "any other criteria that cabinet is using in determining whether or not to defer PBS listing of medicines?", the Secretary of the Department of Health and Ageing Ms Jane Halton replied: "I do not think we can provide any such thing because I do not believe it exists…are there formal criteria, no.; is there an explanation for the ones that were chosen, yes, but in terms of formal criteria, no." Questions as to whether the Minister made a

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[6] 'Patients benefit from new medicines listed on the PBS and NIB', Minister for Health and Ageing, media release, 25 February 2011
http://www.health.gov.au/internet/ministers/publishing.nsf/Content/00FAF51478CA9E29CA2578420003B9F4/$File/nr029.pdf

[7] 'Opening Address to Consumers Health Forum PBS Summit', Minister for Health and Ageing, 29 April 2011
http://www.health.gov.au/internet/ministers/publishing.nsf/Content/F2D512F124949662CA257881001FC9AD/$File/nrsp290411.pdf

[8] 'Interview with Alan Jones – 2GB Sydney', transcript, 15 June 2011,
http://www.health.gov.au/internet/ministers/publishing.nsf/Content/2D2805CFD46592F0CA2578B0000C7A62/$File/NR150611.pdf

[9] 'Interview with Alan Jones – 2GB Sydney', transcript, 21 June 2011,
http://www.health.gov.au/internet/ministers/publishing.nsf/Content/8E02F158FF2B0F13CA2578B6000A5603/$File/nr110621.pdf

recommendation to Cabinet, or asked the department for advice about which of the recommended medicines should be funded or deferred, were taken on notice and answers have yet to be provided[10].

Decision-making of such importance to the community should not be made on a secretive basis, which by definition is incapable of being scrutinized, tested and challenged. It strengthens our concern that the basis for decision-making about PBS listings will not only be influenced by cost considerations (over-lain upon the PBA's legislatively-mandated cost considerations and evaluations), but by an inevitable politicization of decision-making. Those organizations (consumer, clinical and pharmaceutical) with the loudest voices – or the most heart-wrenching patients, or those suffering the current disease of interest – will influence, or determine, what drugs, diseases and patients win the lottery of a PBS listing.

### *(f) The financial impact on the Commonwealth Budget of deferring the listing of medicines*

APMA believes that the financial savings for the Commonwealth Budget of deferring listings will be minimal – and may in fact have unforeseen consequences which cost taxpayers more in the longer term. Hospitalizations, other additional medical costs and service demands and the worsening of a range of conditions as a consequence of being unable to access the deferred medicines will increase expenditure in other areas of the health system – at both the Commonwealth and State level, as well as by private hospitals, private health funds and in workers' compensation and transport accident compensation systems. Consequences which cause people to cease work, or be unable to return to the workforce, will also have implications for social welfare expenditure and taxation revenue. There is currently bipartisan support to encourage and assist people currently in receipt of disability pensions to enter the paid workforce on a part or full time basis. We are aware of many people suffering persistent pain who do (or will) require assistance and support to achieve this laudable objective – access to affordable medication(s) is an important element of that assistance.

There will also inevitably be financial consequences as a result of the increased social isolation and reduced quality of life arising from people being unable to afford medications which could have been accessed had they been available at the price applying to listed medicines. Numbers of people likely to be so affected, the full consequences and the likely costs are virtually impossible to quantify, but a financial impact nonetheless which undermines the putative savings upon which this policy is premised and justified.

If it is seriously argued that the cost of listings to the budget bottom line requires listings to be regularly rejected, perhaps 'life-saving' medicines should be rejected for listing on the PBS, rather than the reverse. After all, saving lives, particularly of the elderly, the chronically ill and/or those without private health insurance, is likely to add significantly to the costs imposed on the health system. Clearly an unacceptable – and indefensible - suggestion. But not inconsistent with the basis and logic of the government's new approach to PBS listing.

### *(g) The consultation process prior to a deferral*

It is APMA's understanding that there is no consultation process undertaken prior to a decision to reject a PBAC recommendation to list a medicine. We note that the Minister indicated to the Consumers Health Forum (CHF) convened summit in Canberra on 29 April 2011 that she had sought Medicines Australia input "on the fairest, simplest way to structure the deferral and reconsideration

[10] Committee Hansard Senate Community Affairs Legislation Committee Tuesday 31 May 2011 http://www.aph.gov.au/hansard/senate/commttee/s83.pdf p 92-93

process" and went on to "extend the invitation to the CHF and its membership". However, when questioned about this and whether anything had occurred at the subsequent Senate estimates hearings on 31 May 2011, DOHA Secretary Jane Halton advised that "it is determined by the financial position of the budge. So, no, I am not aware of anything." This response was immediately clarified by Ms Halton as meaning "returning the budget to surplus"[11].

From a consumer perspective, we do not accept that any such process would ameliorate the adverse effect of this new policy. Should the Government persist with this policy, we do call for the additional secret criteria utilized by Cabinet to decide on which medicines to reject to be publicly released, along with any advice relied upon by Cabinet. Furthermore, a clear timeframe within which consumers can expect that the medicines which have passed the rigorous expert assessment process – but been rejected by Cabinet on cost grounds – will be reconsidered and listed is not an unrealistic expectation. We have no idea of what "returning the budget to surplus" actually means, let alone when it might occur. Is this projected? Or achieved? Or some other measure?

### *(h) Compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010*

Please refer to our comments against (c) above. Whilst consumers are not a party to this bilateral agreement, the new Government policy and approach does not seem consistent support for "a viable and responsible medicines industry in Australia" nor an efficient PBS[12]. APMA does not understand how the new policy can be characterized as consistent with an undertaking "not to implement new policy to generate price-related savings from the PBS during the period of the agreement"[13] is beyond we simple consumers. And, if one were to accept the Government's characterization of its decision as a deferral (rather than rejection – which we most definitely **do not**), how this is consistent with a "best endeavors to implement a maximum time frame of six months for consideration and decision by Cabinet"[14] is also something we cannot understand.

### *(i) Any other related matter*

The likely consequences of this policy for the pharmaceutical industry's capacity and preparedness to continue to fund educational programs and the activities of consumer health organizations activities should not be ignored. Government funding of such activities are limited, and the generic pharmaceutical industry provides little, if any, similar funding.

[11] Committee Hansard Senate Community Affairs Legislation Committee Tuesday 31 May 2011 http://www.aph.gov.au/hansard/senate/commttee/s83.pdf p 87
[12] Clause 3, Memorandum of Understanding September 2010
[13] Clause 4, Memorandum of Understanding September 2010
[14] Clause 29, Memorandum of Understanding September 2010

**Disclosure**

APMA declares that it has received the following sponsorships or benefits from pharmaceutical companies:

| | |
|---|---|
| **2009** | nil |
| **2010** | Less than $7,000 from **Pfizer** as an unencumbered grant to produce our quarterly newsletter Wellbeing |
| **2011** | Less than $8,000 from **Pfizer** as an unencumbered grant to produce our quarterly newsletter Wellbeing<br>Less than $10,000 from **Janssen-Cilag** as an unencumbered grant for an exhibitor booth at the 2011 APS Scientific Meeting & the costs associated with staffing the booth<br>Less than $2,000 from **CSL Biotherapies/Grunenthal** as an unencumbered grant to conduct persistent pain self-management educational seminars in June 2011 |