Senate Community Affairs Reference Committee

Inquiry into Consumer Access to Pharmaceuticals and the Formation of Therapeutic Groups on the Pharmaceutical Benefits Scheme

Supplementary Submission from Medicines Australia

31 May 2010

Supplementary Submission

Medicines Australia welcomes the opportunity to provide the Senate Community Affairs Committee with information requested by Committee members, at the recent hearings into Consumer Access to Pharmaceutical Benefits and the formation of Therapeutic groups on the Pharmaceutical Benefits Scheme. We also take the opportunity through this supplementary submission to reaffirm a number of points presented in our original submission that we believe are central to the argument about Therapeutic Groups but which we believe received insufficient attention during the Senate hearings on the matter.

Medicines Australia represents the innovative pharmaceutical industry. Seven out of every 10 prescriptions dispensed under the Pharmaceutical Benefits Scheme (PBS) are medicines manufactured by a Medicine Australia member company. Eighty per cent of expenditure on the PBS is for Medicines Australia member manufactured medicines. *Crucially, Medicines Australia members also account for greater than 60% of sales in the F2 (the off-patent or "generics") market.*

In this submission, Medicines Australia presents, as requested by the Committee, what the industry believes should be (1) a definition, along with the minimum criteria and evidentiary requirements for establishing "interchangeability on a patient basis"; and (2) an appropriate consultation framework for engaging affected parties when questions of "interchangeability on a patient basis" are being considered. This submission will also (3) table documents that it has received from the current Australian Government concerning considerations on raising the current $10 million threshold beyond which Cabinet must review PBAC recommended medicines prior to listing on the PBS.

Before dealing with these matters, Medicines Australia would like the opportunity to re-affirm a key argument concerning the formation of Therapeutic Groups that was largely overlooked during the hearing: the splitting of the PBS into the F1 and F2 formularies, and the fundamental, different price setting and maintenance principles, which underpin them.

<u>Why TGPs are no longer relevant after PBS Reform:</u>

Whilst Medicines Australia acknowledges that the Committee has hitherto focussed on the issue of establishing why and how medicines come to be regarded as interchangeable on a patient basis for the purposes of inclusion in a Therapeutic Group, we believe that such a focus potentially diverts attention from the core argument concerning the redundancy of the Therapeutic Group policy following the introduction of PBS Reform.

The "interchangeability" requirements subtly cloak what is fundamentally a "savings measure" as a "clinical question". In doing so, it inappropriately directs the focus of the inquiry to the activities and processes of the independent expert advisory body, the PBAC, and away from those ultimately responsible for generating the savings proposals. This is not to suggest that the PBAC is not a genuinely independent body or that its opinion is inappropriately influenced by other concerns. Rather, the legislative provisions provide for a division of powers that enable the Government to generate savings ostensibly based on expert clinical advice on an imprecise and "value-laden" concept for which no ***<u>formal</u>*** definition or guidance has been provided.

This lack of formal advice is made even more curious when contrasted with the hundreds of pages of guidance and assistance that is otherwise provided to assist companies to achieve PBS listings, including highly technical discussions on the evidentiary requirements and acceptable methodological approaches for demonstrating clinical and cost-effectiveness. The Senate Committee is referred to the following as examples of this:

- Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (http://www.pbs.gov.au/html/industry/static/how_to_list_on_the_pbs/elements_of_the_listing_process/pbac_guidelines)
- Indirect Comparisons Working Group (report (http://www.pbs.gov.au/html/pdf/industry/Useful_resources/PBAC_feedback_files/ICWG%20Report%20FINAL2)
- Surrogate to Final Outcomes Working Group report (http://www.pbs.gov.au/html/pdf/industry/Useful_resources/PBAC_feedback_files/STFOWG%20paper%20FINAL)

For completeness sake, Medicines Australia will provide the Committee with its suggested own criteria for establishing "interchangeability" below, but first it is important to direct the Committee to the most important arguments against the continued formation of Therapeutic Groups:

1. Therapeutic Groups are not required to ensure the long-term sustainability of the PBS, the long term efficiency of which is underpinned by both rigorous cost-effectiveness analysis in the F1 market and market competition in the off-patent F2 market.

2. Therapeutic Groups undermine industry confidence in the Australian business environment by permitting the Government to intervene at any point in time without consultation in the market, putting ongoing investment at risk[1]

3. The savings generated from Therapeutic Groups do not outweigh the patient risks and business costs described in Medicine Australia's first submission (including costs to consumers)

To recap: The 2007 PBS Reform split the PBS into two distinct formularies: F1 and F2. The F1 market is for single brand medicines (i.e. typically patented, originator medicines without competition). **It is for *this* market that the oft-cited statement that "*the PBS pays for health outcomes*" *is* relevant**. This is because prices are set through rigorous cost-effectiveness evaluation and reference to *different* medicines used to treat the same conditions. The price paid by Government for these medicines is therefore the price, demonstrated by the clinical trial evidence, to be "value-for-money".

When the patent for an F1 medicine expires, other brands may enter the market and compete with the original medicine for market share. When this occurs a medicine moves into F2. At this point a mandatory 12.5% (soon to be 16%) price reduction applies.

[1] This point reiterated on page 4of the Medicines Australia-Commonwealth Government Memorandum of Understanding effective from 6 May 2010 and announced 11 May 2010).

The link between price and health outcomes as demonstrated by clinical data is *no longer relevant* for medicines once they have moved into the F2 formulary. This is because the price paid for F2 medicines is that which the competitive market sets. Unlike medicines in F1, F2 comprises multiple brands of the same medicines, and these compete aggressively for market share.[2] This competition can drive down the price of medicines dramatically. Certainly, the price reimbursed by the Government becomes significantly lower than the "value-for-money" or efficient price established by the clinical evidence when listed on F1. ***Importantly*, since 2007, *by permitting market forces to determine the price in F2, the Australian Government explicitly severed the link between health outcomes and prices for these medicines.***

It severed the link for two reasons.

Firstly, the Australian Government understood that permitting the competitive market to set prices in the off-patent sector would deliver greater savings to the taxpayer (up to $5.8 billion by its own estimates) than the pre-2007 pricing arrangements.

Secondly, the Australian Government also realised that the pharmaceuticals industry was a high-risk, high-cost business. The elegance of the PBS Reforms was that the Government could extract ongoing savings and efficiencies from the PBS whilst providing industry with the predictable pricing business environment in F1 required for the industry to continue investing in Australia.

The recently signed Memorandum of Understanding between the Commonwealth of Australia and Medicines Australia announced as part of the 2010 Federal Budget explicitly reaffirms these complementary and reciprocal requirements. Strengthened price disclosure arrangements and other adjustments to the pricing policy in F2 have provided the Government with confidence that the market will deliver savings to the taxpayer over and above what it had estimated.

In return, the Australian Government has committed to provide the industry with four years of price-related certainty. **Importantly, this includes a moratorium on the formation on new Therapeutic Groups – an acknowledgement that these create considerable and unnecessary uncertainty for the industry by prematurely causing the transition of on-patent medicines into F2.**

Despite this moratorium, Medicines Australia believes that the Australian Government should go further and remove all legislative and policy provisions governing the formation of Therapeutic Groups.

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[2] All products that are proposed for listing on the PBS have to satisfy the criteria specified in the NHA of being acceptable in terms of their cost and effectiveness over alternate therapies. For new compounds, i.e. where there is no existing molecule they will be allocated into F1 and will do so on the basis of demonstrating either similar or improved effectiveness (as measured in outcomes) compared to existing molecules on the PBS. For F1 both elements have to be examined in detail: cost and effectiveness (or outcomes). For molecules listing on F2 there is a fundamental difference as new compounds entering F2 are Brands of existing molecules i.e. they are the identical molecule but marketed under a different name. In this case the issue of effectiveness is redundant since the outcomes are identical (the molecules are identical and bio-equivalence is the criterion) and the sole remaining criterion that needs to be satisfied is cost.

Linking molecules in F1 to those in F2 bypasses this usual process and these principles and confuses the concept of equivalence with the concept of similar. These terms are not interchangeable. Not only do they differ in interpretation and application but the scientific methods required to prove on or the other differs. Lastly, the regulations that describe these are specific and differ too. Equivalence is assured when molecules are identical and bioequivalent but when they differ require a rigorous and specific assessment to demonstrate equivalence in outcomes for both safety and efficacy. In contrast a molecule may differ in certain aspects from another but on balance produce similar outcomes and thereby meet the requirement specified in the regulations of the NHA of "no worse than" but this does not justify a claim that the products are equivalent.

The F1/F2 split makes Therapeutic Groups redundant for the purposes of ensuring sustainability, and the split also acknowledges that there is no longer a link between health outcomes and price for F2 medicines. The latter removes any theoretical justification for ensuring that medicines deemed to be comparative in health outcomes should be priced identically at any given point in time.

Answers to Questions on Notice from 7 May 2010 Committee hearing

As taken on notice at the 7 May 2010 Committee hearing, Medicines Australia committed to provide the committee with further information and clarification on a number of issues.

Medicines Australia's responses are as follows:

Defining 'interchangeability'

Medicines Australia noted in its testimony that the Government has never provided any formal advice or guidance on what constitutes interchangeability on a patient basis for the purposes of including medicines in a Therapeutic Group; nor has it provided any guidance on the evidentiary requirements for meeting such criteria. (This distinct lack of guidance does not apply to most other areas of the PBS listing process.) As argued above, this is not surprising as the Therapeutic Groups Policy is a savings driven policy, where a decision to make savings is made first, and then the expert committee is later asked to deliberate on an ill-formed clinical question.

Medicines Australia believes that to be interchangeable on an individual patient basis, each of the following needs to be satisfied to have genuine confidence that any given patient can be either initiated or switched between any of the medicines without detriment to their health:

1) The drugs must belong to the same therapeutic class (ATC Level 4) and share a principle pharmacological mechanism of action;
2) The drugs must have identical PBS indications and use restrictions;
3) The PBAC must be satisfied that that the drugs are clinically "non-inferior" across all reimbursed indications;
4) The PBAC must be satisfied that there are no clinically meaningful differences in safety/toxicity profiles across all reimbursed indications;
5) The PBAC must be satisfied that the there are no clinically meaningful differences between the dose-response curves of the drugs under consideration
6) The PBAC must be satisfied that none of the drugs under consideration are clinically superior for an identifiable sub-population;

7) The PBAC must ascertain from relevant clinical experts that the **indifference principle**[3] would apply for members of the proposed Therapeutic Group when initiating therapy; and

8) The PBAC must ascertain from relevant clinical experts that, when choosing to switch therapy due to lack of response, poor tolerability, or adverse event, the prescriber would not usually prescribe a drug under consideration for a Therapeutic Group.

In respect to 3 and 4, the PBAC must be satisfied that the medicines compared meet the criteria of "no worse than" in a two way comparison applied to each product (i.e. that neither product can be claimed to have any likely advantage over the other).

This would be applied to both safety and efficacy and the intent would be that there would be not only no evidence that one product was either better or worse than the other but also that there be a no reasonable probability that one product would be better or worse than any other.

Transparency

Medicines Australia believes that the process of forming therapeutic groups should be transparent and give proper regard to principles of due process and natural justice for those sponsors that will be affected by any decision.

When considering whether two or more drugs should be treated as "interchangeable on an individual patient basis" for the purposes of the formation of a Therapeutic Group, the PBAC must seek and consider comments from the sponsor, and notify the sponsor not less than a full PBS Listing cycle before the relevant PBAC meeting.

MA believes that consideration should also be given to include in the Public Summary Documents any decision by the PBAC to regard two or more medicines as interchangeable on an individual patient basis.

Cabinet Threshold

Medicines Australia has consistently put the case for a substantial increase in the threshold at which Cabinet approval of new PBS listings is required. This is especially so since Federal Labor provided a commitment on 22 November 2007 stating, "Federal Labor believes that there should be no unnecessary barriers to patient access to new PBS medicines and will consider raising the current threshold of $10million in any one year." (See 'Federal Labor Response' as per Attachment 1). The Rudd Government has since considered, but not chosen to raise the threshold.

[3] **The indifference principle** – in choosing to initiate a therapy, the prescriber has no *apriori* reason for selecting a drug over any proposed alternative for a given indication.

Attachment 1

Medicines Australia statement—Medicines Matter to Australians

Federal Labor response

1. **Commit to implement the program of PBS reform legislated in June 2007, to ensure sustainability of our medicines system**

   A Rudd Labor Government will implement the program of PBS reform legislated in June 2007. However, in doing so, we will continue to monitor both the effectiveness of the reforms and their impact on consumers, the generic medicines sector and other stakeholders.

2. **Require the Access to Medicines Working Group to provide an interim report by 1 May 2008 with proposals to resolve outstanding critical issues surrounding timely access to, and reimbursement of, new medicines in the future**

   Federal Labor is committed to ensuring timely access to PBS medicines for the Australian public. We will require the Access to Medicines Working Group (AMWG) to provide an interim report within the first six months of 2008. We undertake to respond to the report of the AMWG in a timely manner.

3. **Substantially raise the threshold at which Cabinet approval of new PBS listings is required**

   Federal Labor believes that there should be no unnecessary barriers to patient access to new PBS medicines and will consider raising the current threshold of $10 million in any one year.

4. **Ensure the community understands that devoting Government resources to new medicines is an investment in Australia's future health and well-being**

   Federal Labor believes that the reforms and investments it plans to make in the health system are essential for ensuring the health of Australia's people and the economy. An absolutely critical element of this is the need to invest in preventive health in order to address the growing problem of chronic illness. Medicines have an important role to play in meeting these objectives. A Rudd Labor Government would ensure that the benefits of its investment in the PBS is clearly conveyed to the Australian community.

CANBERRA

22 November 2007