Interview with Suzanne Hill, Chair, Pharmaceutical Benefits Advisory Committee

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Tags: Pharmaceutical Benefits Advisory Committee

To begin, would you please give a brief introduction to the PBAC?

The PBAC is a statutory committee of government first developed in Australia in the 1940s, which advises the Ministry of Health and Ageing as to what drugs will be listed on the Pharmaceutical Benefits Scheme (PBS). The Minister cannot list a drug on the PBS unless she receives a positive recommendation from the PBAC, so if the PBAC says no, the minister cannot list it on the PBS.

The majority of drugs recommended by the committee are in fact listed on the PBS, but it's not a surety. If the PBAC recommends the drug to be listed, anything over $10 million per year must be taken to cabinet, and the government will determine whether or not, depending on budgeting and expenditure priorities, a recommendation from PBAC will or will not be funded.

In 1991, the National Health Act was changed to require the PBAC to take cost-effectiveness into account in its deliberations. Cost-effectiveness has been in Australia for 20 years, and forms the basis of the PBAC's decision context. It is a very mature system and it serves its purpose of ensuring access to medicines for the community, at a price that the community can afford. This approach is very resonant of the WHO, where I was for the six years before taking this position.

I came into a system that had undergone quite a few changes especially since 2005. I have actually been working with the system in one way or another since 1994, so I had been through much of the development of the cost-effectiveness methods.

When I came back to Australia last year what I noticed was the increased transparency about PBAC decisions, which was a result of the US Free Trade Agreement. This transparency in particular is one of the things that I want to continue. Transparency is your best defence when a system is under stress – and right now the system is under stress from the financial constraints that the government is operating in.

I do not plan any major changes. I do not think that any are needed besides minor methodological developments that will happen.

The Memorandum of Understanding signed between Medicines Australia and the government in 2010 is one of the things that pushes us towards working out how we do managed entry. We have not yet had a submission for that, but it is going to be the major change to the system – not a radical change but a shift.

How do you make sure to continue the PBAC's reputation of transparency?

We should learn from the UK experience of having consumer input into decision making. At the moment we have one consumer representative on the committee, which is a legislative requirement. Obviously for that number to increase the Minister would have to approve and the legislation would have to change. It is hard for a single consumer to be the voice of all consumers in any decision making system, so it would be useful to expand that.

We also have a mechanism on the website allowing consumer comments and having those fed into the committee as the agenda is now published.

It is also hard to have consumers contribute effectively. There is only an electronic comment portal. We need a digestion mechanism to ensure that consumers' voices & views are actually collated and heard. I have been working with various consumer representatives over the past year to see what can be done to improve that input.

Many of our interviewees thus far have expressed concern about the PBS reform, in particular given the major past & upcoming price reductions. What is your response to PBS reform criticisms at the apparent conflict between the government's desire to reward innovation, while sharply reducing the revenues that would otherwise be used to fund such innovation?

The question is: what are you paying for, and how much control do you have over the pharmaceutical sector? When I left in 2005, Australia was paying lower prices for innovative products than its OECD comparators, but relatively high prices for generics. If you want to encourage new products, then generics prices may have to drop to allow head room for

investment.

The PBS reforms introduced in 2007 have been about control of the supply chain to encourage a drop in generics prices, and that created financial space. The challenge then is whether the government will be able to afford to use the efficiencies that it has gained from generics to actually spend it on new products. The PBAC is required under the National Health Act to assess comparative effectiveness, safety and cost. We are also required not to recommend a product that is more expensive than something we already have, unless we are convinced that it is better. It is going to be demanding of the industry, because they will have to put a lot of effort into clinical trials that actually show that their products are really better, and that difference in efficacy or effectiveness can be translated into a difference in price. The usual drug development by industry is incremental in its gains and development, and that is going to be a real challenge. I suspect that the government is going to look for a lot more savings before it allows more expenditure.

Any system needs to be clear about what its overall gains are, and what the aims for healthcare are. If we know that we have three or four different generic molecules and that by allowing competition in the market we can actually allow improved health outcomes at a lower price, then it is irresponsible not to go that way. We need to ask ourselves whether our system is allowing competition appropriately, or whether we have perverse incentives in the system that distort competition and may mean that we do not get best value for money.
At the moment, because Australia has been unpacking its control on generics pricing over the last three years, a lot of things are still in transition, and I believe that there are probably some perverse incentives in the system that are inflating prices inappropriately or are holding up newer versus older generics in the market. Those will gradually be resolved and things will even out. In the end, from the health perspective, we are about health outcomes.

What is the vision of PBAC on high cost high benefit medicine for rare diseases?

Were it high cost and high benefit, then it would not be so difficult. It is usually high cost, and uncertain benefit. That is where the challenge is. In that regard, we do not have discretion under the legal framework to handle those any differently than any other product; if there is a benefit it has to be judged in relation to its cost.

There has been a program called the Life-Saving Drug Program, with its own separate guidelines for some of the very high cost drugs for rare diseases, but like many countries it is now being questioned whether the health gain for these very high cost products is worth the expenditure. The Netherlands for example has made decisions not to spend money on such products for exactly that

reason.

Some of our interviewees have mentioned that, although there are mechanisms in place to speed up the approval of new products, the approval time is still quite long and the predictability of getting products listed on the PBS is decreasing. Would you agree and how is the PBAC working to improve this?

There are three parts to the process. First of all the PBAC has to approve. If the PBAC does not approve, the product will not be listed; if PBAC approves, the product might be listed. That is what companies are complaining about: that it has gone from a definite approval if the PBAC said yes, which meant they only had one hurdle, to a ‘maybe’ after the PBAC approved. Nothing has actually changed other than that the government is exercising its prerogative under the National Health Act, which has always been there and has been exercised in the past, so it is about remembering history a little bit.

There are three parts to it though – there is the PBAC recommendation, there is the pricing negotiation, and then there is approval on the political level. These three parts have always been there. If a company is feeling that things have come less predictable, it could be because the pricing discussions that they are having are much tougher, which in the environment after the global financial crisis is to be expected as well as , in an environment in which the pricing system with the supply chain control is changing. That would be the first hurdle.

Then if the government is fiscally responsible and is worried about its budget, it naturally sets higher demands. Companies are seeing the downstream effects of that as uncertainty, and are seeing basically what other countries are seeing as well in the global financial crisis. It is just the reality of the changing environment that we are working in.

Which factors make the PBS as sustainable as it is?

Firstly the PBS was born out of a joint methodological development in the early stages, with the industry as a partner.

Secondly the Australian system has been sustainable because it has not laid down a hard and fast cost-effectiveness threshold but rather has been allowed to evolve a rough working threshold. It is also allowed to take other factors into consideration when making decisions. We have been able to take the values and preferences of the community implicitly into account and not tie ourselves to a rigid number.

The other strength of the system is that it has been mostly reactive. It does not try and redo all the analysis from scratch, which would be very resource-intensive and demanding. With a population of 22 million the technical capacity that would be needed to do that is high. By saying, ‘Industry, you make the proposal and we will evaluate it,’ rather than doing the proposal from scratch, we ensure keeping the system sustainable.

That said, Australia is still short of health economists, partially because other countries are moving towards the system, people in industry here suddenly being promoted to their head office in New Jersey!

You have been in charge of the organization now for 1 year. What is your vision for the PBS and the PBAC for the remainder of your tenure?

The appointment is for four years. The PBAC has to make sure that its advice is relevant and as accurate as possible. The committee is doing that pretty well and we have to continue to do that. We have to be responsive to both community expectations for access because that is our role in the national medicines policy, as well as to industry expectations for access for business purposes. We have to sit on the fence at times and make sure that both views actually get transferred into that advice.

We have to remain independent because the strength is having an independent advisory committee that people can turn to for a balanced view, without being prejudiced by either side of the spectrum.

Remaining independent is key, as well as being clear and transparent. We need to maintain what my predecessor Lloyd Sansom has managed to do so well over the last decade and develop it to suit the needs of the various stakeholders.

What would be your final message to our international readers?

Australia remains a benchmark system for looking at cost-effectiveness and value-for-money decisions. At the same time it is very conscious that it is trying to balance the needs of industry with health access and health outcomes.

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