



iNova Pharmaceuticals (Australia) Pty Limited

ABN 88 000 222 408

9-15 Chilvers Road

Thornleigh, NSW 2120

Australia

PO Box 101, Pennant Hills, NSW 1715

Telephone (02) 9875 6333

Fax (02) 9875 6416

15 July 2011

Senate Finance and Public Administration Committees

PO Box 6100

Parliament House

Canberra ACT 2600

Re: Keep the PBS Listing Process Independent Based on Expert PBAC Advice

Who are we?

iNova Pharmaceuticals (Australia) Pty Limited is an Australian owned and operated pharmaceutical company. We are also corporate headquarters for iNova Pharmaceuticals (“iNova”) operations across Australia, New Zealand, the Asia-Pacific and Southern Africa.

Everything we do at iNova is driven by creating value for patients, healthcare professionals and the broader community. Testament to this is our knowledge based workers who are pivotal to searching for and developing new therapies to place on the Pharmaceutical Benefits Scheme (PBS) for Australian patients. They also contribute to the 50% of export revenues, investment and jobs benefiting the Australian economy. However, certainty of the PBS listing process is paramount in supporting a business able to provide these outcomes for the benefit of all Australians.

What makes an Australian multi-national healthcare company write to a Senate Inquiry?

We wish for the Australian community to have access to our future new medicines for asthma, chronic obstructive pulmonary disease and a certain type of skin cancer on the PBS. These therapies are expected to provide Australians benefits over existing treatments, improving quality of life and delivering both patient and tax-payer value.

However, for Australians to have timely, reliable and affordable access to these and other new medicines, certainty is required in the PBS listing process, which needs to keep operating independently without undue political or financial influence, supported by consistent and transparent decision making.

It is within this context iNova, as a healthcare company with potential new products to bring to Australians, appreciates the opportunity to provide input into the above Senate Inquiry, focusing on the issues overleaf.

Yours sincerely, ,

Andrew Howden

Chief Executive Officer

1. PBS is a Key Investment in Australia's Health

Listing new therapies on the PBS is a key **investment** in the health of Australians and not a mere cost. These are therapies that have been shown to meet a clinical need and improve health outcomes, for example, increase survival or greater quality of life, often saving costs elsewhere in the healthcare system. Another benefit is that these medicines increase the offering of therapies to meet individual patient needs, which otherwise would not occur if there was a 'one size fits all approach' to managing illnesses in Australia based on few PBS listings.

Importantly, PBS investment is grounded on independent expert PBAC recommendation, which is supported by a well-administered, proven evaluation and listing process. Under this process all medicines for potential PBS listing undergo a very rigorous assessment of effectiveness, safety and *cost versus benefit* to ensure they represent *value for money* for the taxpayer dollar.

In fact, PBS cost is one of several types of cost considered during comprehensive evaluation, which weighs the health improvements and PBS cost of the new therapy against other healthcare costs saved by the new therapy such as less hospitalisation, pathology and fewer doctor visits. Also, productivity gains whereby the new therapy enables an individual to return to work and other everyday activities, compared with alternative healthcare, is often demonstrated during evaluation.

Given this process, people in need of new medicines recommended for listing by the PBAC on the basis they are effective and a worthwhile investment of taxpayer money should not have access denied due to (indefinite) PBS listing deferral. Such delay may potentially create a two tiered system whereby only those able to pay fully for new non-PBS listed medicines can access them, while many Australians with serious illnesses are denied access. *Is this what Australians want?*

The PBS is fundamental investment in Australians' health, and is not a cost containment tool to help manage the Federal Budget back to surplus.

2. Access to Future Therapies Requires Certainty

There is potential opportunity for iNova to make available to Australians via the PBS two new therapies. These represent an advance in the management of asthma and chronic obstructive pulmonary disease (COPD), respectively, the latter of which would be the first of a new pharmacological class offering benefit over existing treatment options.

However, arrangements to bring these therapies to Australian patients require certainty of the PBS listing timeframes which is currently proving difficult in light of the recent PBS deferrals.

Specifically, we can no longer assume the PBS process as outlined in the National Health Act given that Cabinet involvement and the issue of managing the Federal Budget back to surplus have now usurped PBS relevant matters advised by the PBAC including clinical need, effectiveness, safety and value for money in spending tax payer dollars.

Furthermore, iNova is planning for PBS access to an in-house developed therapy, which treats a certain type of skin cancer and represents an advance over current treatments. However, we now question the worth of continuing to invest in this new formulation for Australia since its potential PBS listing could be placed on hold indefinitely.

Respiratory health and cancer are both national health priority areas that iNova would like to continue investing in for the benefit of Australians' health, yet to do this requires certainty of the PBS process and timeframes based on timely implementation of positive PBAC recommendations. However, to allow protracted or indefinite timelines to PBS listing as a 'tool' for managing the Federal Budget, effectively negates a longstanding PBS process that previously worked well in providing Australians timely access to new therapies, supported by the provisions of the National Health Act and the National Medicines Policy.

3. PBAC Independence is Paramount

iNova's opinion is the recent deferral of several new medicines recommended for PBS listing by the PBAC is totally at odds with the role and terms of reference of the PBAC. This committee is an independent statutory expert body established under the National Health Act 1953, who are empowered to make recommendations and give advice to the Minister regarding which therapies should be available on the PBS without interference by the Cabinet.

Indeed, just as the Reserve Bank of Australia is an independent statutory body that makes recommendations without Government influence, so too is the PBAC an expert body of appointed individuals, legislated to operate at arms length from the Government and whose positive recommendations should not be interfered with, yet rather acted upon without delay to benefit Australians' health and the taxpayer dollar.

Under the National Health Act, the PBAC is required to consider **both the effectiveness and cost** of a proposed new medicine compared with alternative therapies. In considering cost and making its recommendations, the PBAC advises the patient populations, PBS quantities, uses and relevant conditions for PBS subsidy. Regarding cost, the PBAC considers both the PBS cost of a new medicine and a range of other relevant healthcare and non-healthcare costs. The new medicine is therefore shown to not only deliver greater health benefits compared with alternative therapies, but also cost savings elsewhere within the healthcare system, as well as enable greater productivity because individuals can return to work or other daily living activities.

Is the Cabinet factoring these cost savings and productivity gains by new medicines recommended for PBS listing into its decision-making?

iNova trusts the Inquiry will give due consideration to the matters raised in this submission. We fully support the role of the independent statutory expert PBAC whose PBS recommendations should be implemented without delay, just as those of other independent statutory bodies such as the Reserve Bank of Australia are implemented without Government influence or interference. We also support the provisions of the National Health Act and National Medicines Policy to enable Australians timely, reliable and affordable access to necessary therapies the PBAC has determined will benefit people's health and represent a good investment of the Australian tax paper dollar. It is upon this basis that we look forward to making available to Australians in the future via the PBS new therapies providing value to patients and taxpayers in the management of asthma, COPD and skin cancer.