Submission to the Senate Standing Committee (References) on Finance and Public Administration in relation to the:

The Government's administration of the Pharmaceutical Benefits Scheme

Committee Secretary
Senate Standing Committees on Finance and Public Administration
Parliament House, Canberra

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Roche Products Pty Limited

Background

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics.

Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammatory and autoimmune diseases, metabolism and central nervous system.

Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management.

Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2010, Roche invested over $9 billion (AUD) in research and development worldwide, including approximately $36 million (AUD) in pharmaceuticals in Australia.

Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan.

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Submission

Roche Products Pty Limited is the Australian affiliate of F. Hoffmann La-Roche Limited (Roche).

The company welcomes the opportunity to make this submission to the Senate Standing Committee (References) on Finance and Public Administration in relation to the Government's administration of the Pharmaceutical Benefits Scheme (PBS).

Roche supports the Pharmaceutical Benefits Advisory Committee (PBAC) as it provides a framework and process by which industry has been able to operate within for a number of years.

Roche believes that the Government's decision to defer any listings on the PBS of medicines recommended by the PBAC is not good health policy. The continuation of this policy has the following consequences:

1. Significant impact on patients with life-threatening illnesses, such as cancer.
2. Questioning the role of the PBAC.
3. Additional delays of new medicines, as uncertain listing timelines impact companies' abilities to have stock readily available in Australia.
4. Politicisation of the PBS listing process.
5. Evaluations of PBS listings on a narrow set of fiscal information results in poor policy.

Significant impact on patients with life-threatening illnesses, such as cancer

Cancer is a major cause of death in Australia, so for patients with advanced forms of the disease, time is precious.[1] In the last decade, new cancer treatments have contributed to a significant increase in life expectancy for those diagnosed with cancer.[2] This dramatic improvement has only been possible because medicines have moved from discovery and development to routine use by in clinicians in a timely manner.

Roche, as a world-leader in developing cancer medicines, has brought many new treatments to patients, which have positively impacted on their survival and quality of life. Any delay in making available a new cancer medicine, such as one indefinitely deferred by Cabinet, may have a significant impact on the lives of current and future cancer patients. One cancer type in which to illustrate this is advanced (metastatic) melanoma.

Every year, over 1,200 Australians die from melanoma.[3] In discussing advanced melanoma, Professor Richard Kefford, Professor of Medicine at the University of Sydney, and Director of the

[1] *Australia's Health 2010*, Institute of Health and Welfare, Canberra 2010
[2] Ibid
[3] Ibid

Westmead Institute for Cancer Research, recently noted "*… there really wasn't any effective treatments to melanoma as the disease was almost entirely resistant to chemotherapy."*[4]

Recently, a number of companies, including Roche, have developed treatments for advanced melanoma which significantly improve clinical outcomes over currently available treatments. Given the ineffectiveness of current treatments, it is critical to provide new medicines to patients quickly and as early as possible in order to achieve the best possible outcomes.

In Australia, a key milestone which allows widespread access to a medicine is its listing on the PBS. If Cabinet was to indefinitely defer the listing of a new treatment for advanced melanoma, as it has with five medicines to date, it would have significant patient consequences for those with this quickly progressing, incurable disease. Any delay caused by a Cabinet deferral restricts options for patients with advanced disease who unfortunately do not have time to wait, and ultimately impedes Australia's progress in tackling life-threatening diseases.

Questioning the role of the PBAC

The PBAC is a world-leading Health Technology Assessment (HTA) agency. The PBAC, as an independent statutory committee, assesses applications for listing on the PBS based on clinical benefit and cost-effectiveness, compared with other treatments for the same condition or use.

The assessment by the PBAC of pharmaceutical medicines is an example of one of the most systematic and well-established processes of any Commonwealth Government spending programme.

The preparation of a submission to the PBAC is a lengthy process requiring considerable economic and clinical information. It takes many months to prepare a submission. This means that the preparation of a PBAC submission is not only costly in terms of the filing fee ($119,500 for a major submission), but is also resource intensive for the sponsor.

Given the rigour of the PBS listing process, it was the believed orthodoxy that a medicine recommended by the PBAC would receive approval for PBS listing by the Commonwealth Government. It was therefore unexpected when the Federal Minister for Health and Ageing announced on 25 February 2011 that the Government would defer the listing on the PBS of six medicines recommended by the PBAC.

The potential to now have a medicine deferred by the Federal Cabinet, after a positive PBAC recommendation, questions the role of the PBAC. We are not calling into question the rigour and expertise of the PBAC but rather that the Government has created uncertainty as to what a positive PBAC recommendation might mean in relation to a PBS listing.

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[4] *Major breakthrough in 'the Australian cancer'*, Sydney Morning Herald, 4 November 2010, available at: http://www.smh.com.au/lifestyle/wellbeing/major-breakthrough-in-the-australian-cancer-20101104-17eyh.html

Additional delays of new medicines, as uncertain listing timelines impact companies' abilities to have stock readily available in Australia

Prior to the announcement of PBS deferrals, it was common practice for pharmaceutical companies, including Roche, to order stock of a PBAC-recommended medicine in anticipation of its PBS listing. The companies would carry the cost and financial risk of this stock because, as noted above, it was the orthodoxy that the medicine would be listed.

Roche has minimum three-month lead time for the ordering of a new medicine for delivery into Australia. With all PBS listing decisions having to go to Cabinet, and with the possibility of being deferred, Roche is unlikely to order any new PBAC-recommended medicine for Australia until a decision by Cabinet has been made to list it. It is no longer commercially sensible to carry the financial risk of stocking a medicine which may not be available on the PBS due to a Cabinet deferral.

This means that even if Cabinet does approve a medicine for listing, patients may experience an additional delay while a company orders stock for Australia. For Roche, this would be a minimum of three months after a positive Cabinet decision.

Politicisation of the PBS listing process

In the announcement of 25 February 2011, the Minister of Health and Ageing made it clear that <u>all</u> future PBS listing decisions, regardless of the magnitude of the net financial cost to Government, would go before the Federal Cabinet.

This decision means that all 20 Cabinet Ministers are now responsible for PBS listings. With this comes a requirement that a Minister would have sufficient understanding and knowledge about all medicines that come before Cabinet for listing.

In addition, Cabinet Ministers are a legitimate focus for communications and persuasion around the listing of individual medicines. Health consumer organisations, peak professional medical bodies, industry and individuals can all provide information and seek to meet with Cabinet Ministers or Ministerial Officials to discuss the listing of specific medicines. This could result in numerous meeting requests and correspondence with these people, negatively impacting on time available for other equally important matters.

With elected politicians now usurping the recommendations of the PBAC, PBS listings are subject and vulnerable to political pressure, with decisions not solely based on rigorous assessment of the

PBAC, as an independent body. This is of particular concern when clear criteria or the expert information relied on by Cabinet when making decisions is not obvious or publicly available.[5]

Evaluations of PBS listings on a narrow set of fiscal information results in poor policy

The Labor Government has made reform of the Australian health system a major policy initiative. One of the key reasons stated for this reform is to stop the *"cost-shifting, blame-shifting and buck-passing"* between the Federal and State Governments.[6]

On 13 February 2011, the Prime Minister, Hon Julia Gillard, announced a new funding deal with the State and Territory Governments. Under the new funding model, the Federal Government will meet 50% of hospital costs. In the media announcement, the Prime Minister and Minister for Health and Ageing stated: *"This will mean a genuinely equal <u>partnership</u> between the Commonwealth and the States and Territories on how growth in hospital costs is paid for into the future."*[7] (Emphasis added).

In its evaluation of medicines for listing on the PBS, the PBAC considers the total cost or saving to the Australia health system of a treatment.[8] This means that in evaluation of a medicine, it is possible the listing will actually deliver a cost saving to the overall health system. A recent example of this is the PBAC's positive recommendation of Roche's medicine XELODA (capecitabine) at its March 2011 meeting. The PBAC Public Summary document states: *"The submission estimated the financial cost/year to the PBS to be less than $10 million in Year 5 with overall annual cost savings to the health care budget, both State and Commonwealth, over the first five years of listing."*[9]

However, the Department of Health and Ageing has stated that in relation to the medicines deferred in February 2011 that:

> *"All the drugs whose PBS listing was deferred had a net cost to the Government's budget. With one exception, that fact that listing was associated with a net cost was known at the time the submission was considered by the PBAC. The Government considers the net cost to the whole of Government including operation of the listing effect on veterans' medicines, medical services and pharmaceutical services."*[10]

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[5] Jane Halton, Secretary, Department of Health and Ageing to Senate Affairs Legislation Committee budget estimates hearing, 31 May 2011. Available at: www.aph.gov.au/hansard/senate/commttee/s83.pdf

[6] Health and Hospitals Reform Commission, Terms of Reference, 20 December 2007, available at: http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/6DB0EDB4CA32D9FECA25741F001483AF/$File/ToRs.pdf

[7] *A Better Deal For Patients*, Media Release, Prime Minister and Minister for Health and Ageing, 13 February 2011, available at: http://www.pm.gov.au/press-office/better-deal-patients-0

[8] *1995 Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee: including major submissions involving economic analyses*, Pharmaceutical Benefits Advisory Committee, available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pubs-pharmpac-gusubpac.htm

[9] Public Summary Document by Product, PBAC, March 2011, available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-capecitabine-march11

[10] Department of Health and Ageing answers to Medicines Australia questions regarding deferrals, April 2011

Roche understands this to mean that when the Federal Cabinet considers a PBS listing, it only considers the costs related directly to the Commonwealth health budget. Unlike the PBAC, it does not consider the other implications, including costs savings, to health expenditure in Australia. Given the Government's commitment to ending blame and cost-shifting, and to building a health funding partnership with the State and Territory Governments, this is a narrow focus.

Conclusion

In summary, Roche believes that the Government's decision to defer any listings on the PBS of medicines recommended by the PBAC is not good health policy. The current situation: may have significant impact on patients with life-threatening illnesses, such as cancer; questions the role of the PBAC; may result in additional delays of new medicines once they become listed on the PBS; leads to politicisation of the PBS listing process; and, leads to evaluations of PBS listings based on a narrow set of fiscal information.

Roche asks that the Government policy of PBS deferrals is discontinued and previous practice reinstated.