Shadow Minister for Health and Medicare

31 May 2018

Mr Grant Hehir
Auditor-General
Australian National Audit Office
Urgent via email: grant.hehir@anao.gov.au

Dear Auditor-General

I am writing to request an urgent audit into the circumstances surrounding the listing of afatinib (Giotrif®) on the Pharmaceutical Benefits Scheme (PBS) on 1 May 2018.

Labor welcomes the listing of this lung cancer medicine on the PBS – particularly as it comes more than four years after the listing was recommended by the independent Pharmaceutical Benefits Advisory Committee (PBAC).

While a future Labor Government would maintain subsidised access to afatinib via the PBS, the medicine has been listed under a special pricing arrangement (SPA). Serious concerns have been raised that the SPA does not meet the Department of Health's eligibility criteria.

This was reportedly[1] in order to secure the manufacturer's support for a trial of new payment arrangements announced in the 2018 Budget. In Senate Estimates yesterday, Department of Health officials confirmed that the Deed of Agreement for the drug's listing included both the SPA and the manufacturer's participation in the trial.

As you would be aware, the PBS is a significant investment by the Commonwealth, with 2018-19 Budget Paper 1 showing estimated expenses of over $12 billion in 2018-19.

Given this level of expenditure, successive governments and oppositions have respected the rigour of the PBS process – including in relation to SPAs. Any action by the Government and/or Department which perverts the SPA process in order to achieve the Government's separate policy aim on the payments trial would undermine the PBS process and raise serious probity concerns.

[1] For example, see 'There must have been a formal review?', *Pharma Dispatch*, 30 April 2018

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At Senate Estimates yesterday, Department of Health officials claimed that afatinib was eligible for a SPA because it had been "recommended for listing in comparison with a medicine which has a similar arrangement".

However, the SPA for the medicine cited by Health officials – erlotinib or Tarceva® – was removed in April 2014.

This was the very basis on which afatinib was not granted a SPA in 2014, or when the drug's manufacturer sought re-consideration in 2015.

The Department's revised advice in late 2017 or early 2018 came at the same time as it was negotiating with the manufacturer regarding the payments trial.

At Senate Estimates yesterday, officials also confirmed that:

- Afatanib's listing was a "highly unusual circumstance";
- This is the only SPA that has been granted contrary to the advice of the PBAC; and
- The Department discussed afatanib's eligibility for a SPA with an adviser to the Minister for Health prior to providing formal advice to the Minister.

I therefore seek your urgent investigation of the circumstances surrounding this listing.

I would be happy to discuss this issue at your earliest convenience.

Yours sincerely,

Catherine King

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