



Australian Government
Department of Health

Ref No. MC15-001156

Elizabeth Hart

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Dear Ms Hart

I refer to your correspondence of 21 January 2015 to the Prime Minister, the Hon Tony Abbott MP, regarding vaccination policy and practice in Australia – lack of transparency and accountability. Your letter has been referred to the department by the Minister for Health.

Within the Department of Health there are four major technical committees advising on vaccines and immunisation:

- Australian Technical Advisory Group on Immunisation (ATAGI);
- Advisory Committee on the Safety of Vaccines (ACSOV);
- Australian Influenza Vaccine Committee (AIVC); and
- Pharmaceutical Benefits Advisory Committee (PBAC).

The primary role of all these committees is to provide quality evidence based advice to myself, through my Department. Due to the calibre of people selected to provide advice there may be instances where some members are involved in vaccine research.

All advisory committees' recommendations on vaccines are based on the best scientific evidence available from both published and unpublished literature. Any potential Conflicts of Interest (CoIs) of advisory committee members are required to be declared on the nomination to the committee; at the beginning of every calendar year; and before every meeting. These CoIs are then assessed in accordance with the committee's CoI policy. The Department takes integrity, transparency and the CoI process very seriously. Advisory committee secretariats are continuing to improve the management and transparency of potential CoIs of advisory committee members.

The PBAC is an independent, expert advisory body comprising doctors, other health professionals and a consumer representative. It is established in accordance with section 100A of the *National Health Act 1953* (the Act) to advise on inclusion of the drugs, medicine preparations and vaccines on the Pharmaceutical Benefit Scheme (PBS) or on the National Immunisation Program (NIP). PBAC roles and functions are defined under section 101 of the Act.

In regards to the Therapeutic Goods Administration's (TGA) Advisory Committee on the Safety of Vaccines (ACSOV) and the Australian Influenza Vaccine Committee (AIVC), the processes related to CoIs are described in regulation 42 (4) to (7) of the Therapeutic Goods Regulations 1990 and detailed in the TGA advisory committee guidelines. Declarations of interests, managing conflicts of interests and confidentiality obligations, which is publicly available on the TGA website <https://www.tga.gov.au/publication/tga-advisory-committee-guidelines> The TGA website also provides short biographies of members of the ACSOV and the AIVC.

The ATAGI provides technical advice to myself and the PBAC on the medical administration of vaccine available in Australia. ATAGI is also responsible for producing the Australian Immunisation Handbook and making recommendations regarding the scheduling of vaccines on the National Immunisation Program Schedule.

The ATAGI has an established process for the declaration and, if necessary, the management of CoIs. At its 19 – 20 February 2015 meeting ATAGI reviewed the COI policy and agreed to publish details of the CoIs of its members on the Immunise Australia website to improve transparency. It is anticipated this information will be published in March 2015.

Thank you for bringing this matter to the Government's attention.

Yours sincerely

**Immunisation Branch
Department of Health**

More information on the committees could be found on the following websites:

ATAGI

<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/advisory-bodies>

PBAC

<http://www.pbs.gov.au/info/industry/listing/participants/pbac>

<http://www.pbac.pbs.gov.au/>

TGA: – ACSOV and AIVC

<https://www.tga.gov.au/statutory-advisory-committees>

<https://www.tga.gov.au/committee/advisory-committee-safety-vaccines-acsov>

<https://www.tga.gov.au/committee/australian-influenza-vaccine-committee-aivc>