

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Education and Employment Legislation Committee

COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023

03 August 2023

PDR Number: IQ23-000059

Number of TGA executives, members of panels, or advisory bodies, have been employees of big pharmaceutical companies and managing conflicts of interest

Spoken

Hansard page number: 24

Senator: Alex Antic

Question:

Senator ANTIC: Yes, absolutely. Of the six leading regulators in Australia, Canada, Europe, Japan, the UK and the US, Australia's TGA has the highest proportion of budget from industry fees at 96 per cent. In 2020 to 2021, the TGA approved nine out of every 10 drug company applications. Does the TGA consider that it is horribly conflicted by virtue of that industry funded model?

Prof. Lawler: No.

Senator ANTIC: What percentage of current members of the TGA executive of the Health Products Group, the advisory panel, or any of the other advisory bodies under the executive arm of the Therapeutic Goods Administration are prior employees of big pharmaceutical companies?

Mr Henderson: I don't have an answer to that question, Senator Antic. I will take that on notice.

Senator ANTIC: Can you take that on notice?

Mr Henderson: Yes. Of course, we do have detailed processes around managing conflicts of interest within the TGA and our committees, so I am happy to provide them as well.

Answer:

All Department of Health and Aged Care (the department) employees are required to disclose actual or apparent conflicts of interest in accordance with requirements of the Australian Public Service employment and financial management legislative frameworks, the department's Accountable Authority Instructions, Finance Business Rules and Conflict of Interest Policy.

The department's Conflict of Interest Policy identifies a list of personal interests that employees may need to disclose if a connection can reasonably be made between the interest and the employee's duties. The department has reviewed our register, and no current members of the Therapeutic Goods Administration Executive have declared previous employment with pharmaceutical companies.

Declaration and conflict of interest in our committees

The recruitment process to appoint Committee members (which are appointed by the Minister for Health following an external recruitment process) calls for applications from scientific and medical experts with expertise in relevant clinical or scientific fields or from others with expertise with consumer health issues. Members are therefore appointed to provide professional advice in relation to matters coming before the committees based upon their knowledge and expertise.

Applicants must submit a '*declaration of interests in support of application*' when seeking membership to a statutory advisory committee. In addition, Section 29 of the PGPA Act, expressly require the disclosure of direct or indirect material personal and pecuniary interests by members of the statutory advisory committees.

A written '*disclosure of interest declaration*' is also required at various times during a committee member's term of appointment including on appointment, annually during their term of appointment, prior to each committee meeting (including any interest in relation to specific agenda items), and at the commencement of each meeting. Members are also required to notify the Chair and secretary, in writing, of any additional interests as soon as reasonably practicable, during the term of their membership.

The regulations also state that unless the committee determines otherwise, a member who has disclosed a material personal interest in relation to an agenda item will be excluded from the meeting during any deliberations regarding the advice or recommendations to be given on that agenda item. The member who has declared the interest is also unable to be present when the committee is determining whether the member may participate. Disclosures must be recorded in the minutes of committee meetings.

The small number of potential members in Australia with the necessary specialist expertise to contribute to the committees means that conflicts of interest may arise around particular items. In these cases it is sometimes appropriate for a member to make a scientific/medical presentation to the committee on the condition and medicines but then absent themselves from any committee discussion or recommendation-making on the item.

Upon appointment to a statutory advisory committee, members are also required to sign the Deed of undertaking in relation to confidential information and conflict of interest (the Deed). The Deed sets out members' obligations relating to disclosure of interests. In accordance with the Regulations, the Minister may terminate an appointed member's appointment if they fail to comply with the disclosure of interest requirements.

Any temporary members, invited experts and observers are also required to declare any interests prior to a committee meeting.