

TGA gagged on Trans-Tasman

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It is evident that the Therapeutic Goods Administration (TGA) and Medsafe have been banned from speaking on issues related to Trans-Tasman harmonisation until the New Zealand election is decided, delegates at last week's annual Association of Clinical and Regulatory Scientists were told.

Speakers from both regulators, whose presence was eagerly anticipated so they could be quizzed on the progress of the Trans-Tasman project, failed to appear at the last minute. Their absence was condemned by industry representatives both from the platform and on the floor.

Judith Griffin, senior manager strategic relations and policy at Merck Sharp & Dohme and leader of the Medicines Australia trans-Tasman working group, told the meeting it was clear that the regulators had been gagged by the Interim Ministerial Council which is overseeing the establishment of the Joint Trans-Tasman Agency.

She said that drafting of the implementation law had fallen behind schedule because the TGA had not been able to secure a draftsman from the government and had now appointed a consultant legislative draftsman who was continuing to work on the draft bill. According to the NZ Researched Medicines Industry Association, the Therapeutic Products Bill is expected to be tabled in the NZ Parliament this month and is scheduled for the current session of the Australian parliament.

Medicines Australia CEO, Kieran Schneemann, said that industry was still "flying blind" and expressed disappointment at the absence of both regulators from the trans-Tasman session.

He said that following a conversation with the acting head of the TGA, he sensed that in the light of the forthcoming NZ election - due no later than September - "neither the Australian government or the public service wanted to attend or contribute to the session".

However, delegates who had attended the annual conference of the NZ Association of Clinical Research, NZ's equivalent to ARCS, only a week previously said Medsafe's Principal Technical Specialist, Dr Stewart Jessamine, had appeared and spoken at length on the project.

In an ironic twist, Australian parliamentary secretary for health, Christopher Pyne, who oversees the TGA, issued a press release last Thursday - the day after the ARCS conference wrapped up - saying the regulator had improved its communications with stakeholders in response to an unpublicised review which had taken place last year.

He said the regulator had participated in a number of seminars in conjunction with industry associations and had made presentations at the ARCS conference, referring to non-trans-Tasman sessions at which TGA staff had appeared.

"The TGA is confident that it can build on its current communications with industry to improve the consultative process," Mr Pyne said.