

## **Letter 7 Administrative law aspects of the proposed Trans-Tasman Therapeutic Goods Agency (1)**

Following is the first of two letters written by the Council as part of its involvement in the creation of a joint agency to regulate therapeutic products in Australia and New Zealand. The Council was invited by the Therapeutic Goods Administration to be involved in discussions about mechanisms for merits review of the decisions of the proposed agency.

In view of his portfolio responsibilities, the Council set out its opinion on the preferred mechanism in this letter to the then Attorney-General, the Hon. Daryl Williams AM QC MP. The Council suggested two possible options: either encouraging New Zealand to create its own equivalent of the Administrative Appeals Tribunal or appointing New Zealand members to a 'rebadged' form of the Tribunal.

This advice was not published in the Council's 2002–03 annual report because the treaty establishing the joint agency was still being negotiated. Further information about the merits review mechanism finally agreed upon can be found in the preface to Letter 8.

25 February 2003

The Hon. Daryl Williams AM QC MP  
Attorney-General  
Parliament House  
Canberra ACT 2600

Dear Attorney-General

### **Administrative law aspects of the proposed Trans-Tasman Therapeutic Goods Agency**

As you are aware, negotiations are currently taking place between Australia and New Zealand in relation to the establishment of a Trans-Tasman Therapeutic Goods Agency (TTTGA), consistent with the Trans-Tasman Mutual Recognition Arrangement.

Key issues in the negotiations are the accountability and review bodies which would be available in both countries. A particular problem is the absence of a comparable body in New Zealand to the Commonwealth's Administrative Appeals Tribunal.

The Administrative Review Council believes that these issues are of broader importance as they have the potential to set a precedent for future trans-national regulatory schemes between Australia and New Zealand.

*Discussions about merits review*

The Council has been involved in discussions in relation to an appropriate merits review mechanism for the proposed TTTGA at the invitation of the Therapeutic Goods Agency (the TGA) in the Department of Health and Ageing.

In the discussions, the Council has adopted as its starting point the position that there should be no diminution of the rights and entitlements currently available to applicants for review of decisions in relation to therapeutic goods by the Administrative Appeals Tribunal.

*Essential elements of merits review*

These rights and entitlements include:

- de novo merits review of decisions by an independent and impartial review body in accordance with the rules of procedural fairness
- power on the part of the external review body to affirm, vary or set aside the original decision or to remit the matter to the original decision-maker for reconsideration in accordance with any directions or recommendations of the review body
- power to require the agency whose decision is being reviewed to provide the review body with a copy of all documents relied upon by the decision maker in making the decision, and a duty to make a copy of those documents available for inspection by the applicant for review
- power on the part of the external review body to inform itself as considered by it to be appropriate and that it not be limited by the rules of evidence
- an appeal right on, and a right to refer, questions of law to a court; and
- a right to reasons for decisions.

*Different opinions about appropriate merits review tribunal*

The Council is of the view that the AAT should have a continuing role in relation to decisions of the TTTGA. The TGA favours establishing a separate TTTGA review body.

The difficulty with that solution is that matters will need to be heard and determined in both Australia and New Zealand.

*Options – AAT or dual review bodies*

The Council has suggested two possible options to achieve this objective.

First, New Zealand could be encouraged to establish its own permanent merits review body with jurisdiction to hear complaints from New

Zealand. If this option was adopted, then matters could be determined in either country by the respective generalist merits review body.

To encourage consistency in decision making between the two tribunals, strategies could be adopted such as requiring each tribunal to have regard to decisions of the other and provision for members of one tribunal to sit on the other. These strategies are adopted in the *Trans Tasman Mutual Recognition Act 1997* in relation to the AAT and the Trans-Tasman Occupations Tribunal of New Zealand.

Alternatively, New Zealand members could be appointed to the AAT, which in the exercise of its jurisdiction with respect to decisions of the TTTGA could sit in either Australia or New Zealand. A new trans-Tasman division of the AAT could be established, or the tribunal could be otherwise 'rebadged' when exercising its trans-Tasman jurisdiction.

The Council notes that there are no restrictions under the AAT Act upon the appointment of New Zealand citizens as ordinary members of the tribunal. While appointments to more senior positions require admission to practise in an Australian court or judicial office, only a minor amendment to the Act would be required to permit the appointment of New Zealanders to more senior membership positions for the limited purpose of hearing matters arising under trans-national regulatory schemes between our two countries.

#### *Maintaining our current administrative review procedures*

While acknowledging that there are sensitive sovereignty issues surrounding the creation of the proposed TTTGA, the Council is concerned that this issue not undermine our current Commonwealth merits review system. In the Council's view, the creation of a specialist tribunal could provide an unwanted precedent for the establishment of further trans-Tasman tribunals, potentially with rights and entitlements different to, and possibly less than, those currently available under the Australian Commonwealth merits review system.

This outcome would be contrary to the Government's policy of consolidating tribunals in the proposed Administrative Review Tribunal, rather than establishing new ones.

Another aspect of the TGA's approach of concern to the Council is the suggestion that the AAT is not an appropriate merits review body for therapeutic goods because of the subject matter of the appeal and the 'adversarial' nature of the tribunal. The TGA has indicated that it would prefer reviewers to adopt an inquisitorial approach, although it remains less than clear what is meant by the TGA when using this term. In the Council's view, the procedures of the AAT are sufficiently flexible to accommodate an inquisitorial approach where appropriate and that the technical or scientific nature of subject matter does not of itself preclude merits review, given the capacity to appoint specialist members to that body.

These issues may point to the need for some modifications to the AAT's procedures or membership but are not grounds for replacing the AAT's jurisdiction.

*Recommendation*

In summary, the Council believes that it is highly desirable that the expertise and infrastructure of the AAT be utilised in relation to decisions of the proposed TTIGA.

The provision of ready access for individuals to independent and high quality review of decisions that is inexpensive, prompt, informal and effective has resulted in a positive transformation in the decision making procedures of government in this country.

It would be unfortunate if the move to trans-national agencies resulted in a retreat from these principles that have served Australia so well over the past twenty-five years.

It would also be unfortunate if the establishment of a separate review procedure on this occasion set a precedent which resulted in the creation of more single-purpose review tribunals in future, rather than adapting our existing, proven administrative review tribunal and procedures.

Yours sincerely

A handwritten signature in black ink, reading "Wayne Martin". The signature is written in a cursive style and is positioned above a horizontal line.

Wayne Martin QC  
President