

## **Letter 8 Administrative law aspects of the proposed Trans-Tasman Therapeutic Goods Agency (2)**

Shortly after writing to the Attorney-General about merits review of decisions of the proposed trans-Tasman therapeutic products agency (Letter 7), the Council also conveyed its views to the Secretary of the Department of Health and Ageing, the portfolio agency of the Therapeutic Goods Administration.

The Council received a response from the Secretary, confirming that it was intended that the merits review mechanism for the proposed agency would fit within Australia's existing approach to merits review. The Council also continued to be involved in discussions with the TGA and the Attorney-General's Department.

The merits review mechanism finally agreed by Australia and New Zealand provides for a separate review tribunal in each country, with panels drawn from a common pool of members. In Australia the Administrative Appeals Tribunal will function as the review tribunal, possibly with some additional members with expertise in relevant areas. New Zealand is expected to set up a new tribunal. Internal review will be mandatory before external merits review.

Existing merits review rights in Australia in relation to therapeutic products will be maintained in the new scheme. The AAT's existing rules of procedure will apply in Australia, but capacity is being provided to modify these if necessary to take into account the joint nature of the scheme and enable the two review tribunals to work cooperatively. The regulatory decisions of the new agency will be given effect in both countries, as will the decisions of either review tribunal.

11 March 2003

Ms Jane Halton PSM  
Secretary  
Department of Health and Ageing  
GPO Box 9848  
CANBERRA ACT 2601

Dear Secretary

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

I am writing to inform you of a letter written recently by the Administrative Review Council to the Attorney-General in relation to the proposed Trans-Tasman Therapeutic Goods Agency (TTTGA).

As you know, 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 Administration (the TGA) in your Department.

In its letter to the Attorney-General, the Council addressed several issues over which the viewpoints of the Council and the TGA apparently diverge.

#### *Role of AAT*

The absence in New Zealand of a review body comparable to the Administrative Appeals Tribunal has been a particular issue in the Council's discussions with the TGA.

The Council does not share the TGA's preference for establishing a separate TTTGA review body. Rather, the Council believes that the AAT should have a continuing role in relation to the review of decisions of the TTTGA and that there should be no diminution of the rights and entitlements currently available to applicants for review of decision by the AAT.

#### *Essential elements of merits review*

These 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.

#### *Broader concern*

At the broader level, the Council is concerned that the establishment of a separate TTTGA review body could undermine the current federal merits

review system by providing an unwanted precedent for further trans-Tasman tribunals.

The proliferation of tribunals, each potentially with rights and entitlements different to, and possibly less than, those currently available, would be an undesirable outcome for the federal merits review system. Such a development would also be contrary to the Government's policy of consolidating tribunals in the proposed Administrative Review Tribunal, rather than establishing new ones.

#### *Merits review options*

Having regard to these considerations, two possible merits review options have been suggested by the Council.

The first is that New Zealand be encouraged to establish its own permanent merits review body with jurisdiction to hear complaints from New Zealand. Under this model, matters could be determined in either Australia or New Zealand by the respective generalist merits review body.

The second option involves New Zealand members being appointed to the AAT. In the exercise of its jurisdiction with respect to decisions of the TTTGA, the AAT 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.

#### *Other issues*

The Council does not share the TGA's concerns relating to the review of specialised decisions by the AAT. Contrary to the position taken by the TGA, the Council is firmly of the view that, where appropriate, the procedures of the AAT are sufficiently flexible to accommodate what the TGA has termed an 'inquisitorial' approach in relation to such decisions.

Additionally, the Council considers that the technical or scientific nature of the subject matter of a decision does not in itself preclude merits review by the AAT, given the capacity to appoint specialist members to that body.

While these issues may point to the need for some modifications to the AAT's procedures or membership, the Council's view is that they are not grounds for replacing the AAT's jurisdiction.

#### *Conclusion*

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.

As suggested by the Council in its letter to the Attorney-General, it would be unfortunate if the move to trans-national agencies resulted in a retreat

from these principles of open government 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.

I trust that this letter will be of assistance to you. Should you wish to discuss any of the matters raised in the letter in more detail, the contact officer in the first instance is Margaret Harrison-Smith of the Council Secretariat, who may be contacted on telephone 6250 5800.

Yours sincerely

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

Wayne Martin QC  
President