

THE
FURTHER INTERIM REPORT
OF THE WAITANGI TRIBUNAL
IN RESPECT OF THE
ANZTPA REGIME



WAITANGI TRIBUNAL REPORT 2006

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WAI 262

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The cover design by Cliff Whiting invokes the signing of the Treaty of Waitangi and the consequent interwoven development of Māori and Pākehā history in New Zealand as it continuously unfolds in a pattern not yet completely known

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ABBREVIATIONS

ANZTPA Australia New Zealand Therapeutic Products Authority

TWKO Te Waka Kai Ora o Aotearoa

'Wai' is a prefix used with Waitangi Tribunal claim numbers

THE FURTHER INTERIM REPORT OF THE WAITANGI TRIBUNAL IN RESPECT OF THE ANZTPA REGIME

1. BACKGROUND

On 4 September 2006, counsel for Ngāti Kahungunu made an application for urgent interim recommendations. The application related to a Crown proposal to introduce legislation to create a trans-Tasman therapeutic products authority in New Zealand (ANZTPA). Claimants argued that the proposal would introduce a new and complex regime to regulate the practice of dispensing Māori medicine or rongoa Māori, and would do so without any or any adequate consultation. We were advised that the legislation would be introduced into the House on or after 10 October 2006. We had therefore to consider the matter with some urgency and without the benefit of comprehensive evidence or full argument. Counsel for Te Waka Kai Ora o Aotearoa (TWKO) joined in that application, as did all other claimants. On 8 September 2006, this Tribunal issued an urgent interim report recommending that the Crown engage with the claimants in a consultation process in respect of the issues raised by the application. We indicated that the matter would be reassessed during the Tribunal's fourth hearing week ending on 29 September.

In the event, claimants and the Crown held one consultation meeting on 21 September 2006, but no agreements were reached at that meeting either in relation to a consultation process or in relation to the substantive matters at issue.

At our fourth hearing week, counsel for Ngāti Kahungunu advised us that Ngāti Kahungunu were prepared to rely on the expressed intention of the Crown not to upset the current exemption under the Medicines Act 1981 for rongoa practitioners. Counsel advised us that Ngāti Kahungunu were prepared to engage further in a good-faith consultation process on that basis. Counsel for Ngāti Kahungunu accepted that implementing legislation would be introduced into the House at some time on or after 10 October 2006 and that the effect of this would be to remove the jurisdiction of the Tribunal to further inquire into that Bill, at least until its final enactment.

Counsel for TWKO, whose claim relates entirely to the ANZTPA regime, were not prepared to abandon their application for urgent interim recommendations. All claimants other than Ngāti Kahungunu supported the TWKO stance. The ANZTPA agreement itself was entered into between Australia and New Zealand on 10 December 2003. As the name implies, it is an agreement between the parties that a common regulatory regime will be introduced in respect of therapeutic products. This necessarily includes rongoa Māori. Implementing

legislation is proposed in both countries and rules are to be promulgated pursuant to the legislation by a ministerial council comprising a New Zealand Minister and an Australian Minister. The operational arm of the council is to be an agency run by a board. The agency will have regulatory functions of its own under the rules and these will be performed by the managing director. A series of expert advisory committees is to be established in relation to matters such as prescription medicines, medical devices, adverse reactions, over-the-counter medicines, and complementary medicines.

By agreement, the ministerial council can exempt certain categories of medicine. In this case, it is agreed by both Ministers that the current Medicines Act regulatory exemption will continue in respect of small-scale dispensing of rongoa.

Draft rules have been released by the ministerial council for consultation. There are currently two sets of rules: one in respect of technical standards for medicines and the other relating to the administration of the regime. Though the rules have been published, they are clearly a work in progress. There are a number of gaps in their provisions.

It is clear that the new regime will represent an entirely new approach to the regulation of medicines in New Zealand. Most particularly, the regime will regulate complementary medicines to some extent and so will affect some aspects of the production, dispensing, and sale of rongoa Māori, where this is larger than domestic scale.

2. THE ARGUMENTS

Mr Pou for TWKO advanced three propositions in support of his application. They were as follows:

- (a) The proposed introduction of the ANZTPA regime represented a window of reform opportunity. If Māori did not take steps now to ensure that any new regime was fully Treaty consistent, an inconsistent regime would be in place for a very long time. Quite correctly, in our view, Mr Pou did not couch his argument on the basis of fresh prejudice under the proposed regime. Given the clearly stated intention of the Crown to maintain the rongoa Māori exemption already available under the Medicines Act 1981, he could hardly have done so.
- (b) TWKO argued that the effect of section 8 of the Treaty of Waitangi Act 1975 would be to exclude the Tribunal from any inquiry into the proposed legislation once it was before the House. Mr Pou argued that the opportunity for the Tribunal to intervene and measure the proposed regime for Treaty consistency was now. Any delay would render the utility of the inquiry nugatory.
- (c) It was argued that the introduction of a regime in which New Zealand decision-making is shared with Australia would place a new obstacle between the Crown in New Zealand and the discharge of its Treaty obligations to Māori. This was because,

according to Mr Pou, decision-making would now be shared with a much larger and more powerful party (Australia), which owed no Treaty obligations to Māori.

All claimant counsel who joined TWKO in its application (including TWKO itself) argued forcefully that such limited consultation as had occurred between the Crown and claimants had been inadequate and mean-spirited. Counsel argued that this failure in itself was good reason to recommend a delay in the introduction of the legislation.

The Crown filed submissions in reply on 2 October 2006. The Crown argued as follows:

- (a) good-faith consultation had occurred both prior to the meeting on 21 September 2006 and at that meeting;
- (b) there was ample room for further discussion and that opportunity should be taken;
- (c) there is no irreversible prejudice to Māori because of the Crown's intention to keep the Medicines Act exemption for rongoa under the new regime; and
- (d) all substantive issues remain to be dealt with under the ANZTPA rules, so the introduction of the ANZTPA Bill will not prevent the Tribunal from addressing those issues. (We took this to mean that the Crown makes no claim that the Tribunal is prevented from considering the draft rules under the Bill while the Bill is in the House.)

3. APPLICABLE PRINCIPLES

Although the Crown defended the application on the basis that it was an application for an urgent hearing, the urgent hearing was effectively held when TWKO's case was heard on 28 and 29 September. Instead, the application was for an urgent interim recommendation to the Crown that it delay the introduction of legislation implementing the ANZTPA agreement until after proper consultation had occurred. There are therefore two important elements in the application warranting careful consideration. The first is that the application was for urgent interim recommendations – so urgent indeed that there was insufficient time to consider the proposed regime in any real depth or to hear any evidence from the Crown in support of its proposed course of action. The second element is that the application relates to proposed legislation. This element introduces special considerations as discussed below at section 3.2.

3.1 Urgent interim recommendations

As to the standard generally for urgent and interim recommendations, two principles are applicable. First, it is now well established that the claimants must make out some case that the prejudice they are likely to suffer will be significant and irreversible. The standard is relatively high but not impossibly so. The claims made must be at least arguable on the limited

information that is usually available on applications of this kind. Similarly, though irreversibility is a strong concept, it is a standard that must apply in the real world. For example, the theoretical ability of Parliament to repeal that which it has enacted cannot be an answer if there is a substantive argument that the claimants' Treaty position will be harmed by the legislation.

Secondly, there should be no reasonable alternative to urgent interim recommendations. This category of remedy ought properly to be seen as an option of last resort. But, again, it must be a last resort in the real world. For example, further consultation in matters where the evidence points clearly to an executive with a closed mind is no real alternative at all.

Thus, interim recommendations issued on an urgent basis can be made by the Tribunal, even where the information before it is insufficient for a comprehensive testing of the issues, but we should be satisfied of two things:

- (a) the claimants have an arguable case that they will suffer irreversible prejudice by the proposed Crown action; and
- (b) there are no reasonable and realistic alternatives to such recommendations.

3.2 Proposed legislation

Where the proposed Crown action is the introduction of legislation into the House, additional considerations apply in our view. Though the Tribunal's powers are only recommendatory, it is important that the Tribunal respects the right of a democratically elected government to put a settled legislative proposal to the New Zealand Parliament. There is an obvious wider public interest in the Crown being able to pursue legitimate policy objectives as the government of the day and an equally powerful public interest in a sovereign parliament being able to consider any legislative proposal it wishes. Against these interests are Treaty considerations which provide a counterbalance to the pressures of majoritarian rule. We must look to:

- (a) the nature of the Māori Treaty interest which claimants claim to be affected by the proposed legislation;
- (b) the level of prejudice to that interest if the legislative proposal is enacted;
- (c) the availability of alternatives to withdrawal of the Bill or delay; and
- (d) the fact that introduction of the Bill removes the possibility for a Treaty-focused debate at least during the legislative process.

Taken together, the fact that urgent interim recommendations are sought on the basis of limited information and limited opportunities to test that information, and the fact that the application relates to proposed legislation, suggest we should proceed with caution. In particular:

- (a) the Tribunal should not make recommendations lightly in this case; and

- (b) any recommended interference should be strictly proportionate to the arguable prejudice.

4. THIS APPLICATION

4.1 The effect of the proposal on the status quo

The Crown has reiterated on a number of occasions that the exemption currently contained under the Medicines Act 1981 which excludes medicines made by individual practitioners for an individual patient – according to the Crown called extemporaneous compounding – will be exempt under the new regime also. This has the effect of excluding from both the current and the proposed new regime home-based or small-scale rongoa dispensing and treatment. What is less clear is the extent to which the retail sale of rongoa products and services will now be caught within the ANZTPA regulatory regime when under the Medicines Act they were not caught because they made no therapeutic claim. That distinction between dietary supplement and medicine is now to be removed. It appears that it is at least possible (though there was little evidence on the point) that Māori retailing rongoa products as dietary supplement are not caught now, but will be in the future under the new regime. We heard extensive evidence from commercial operators about the additional costs that will be imposed under the new regulatory regime but little from Māori producers on that issue.

4.2 The interests of the parties

The Crown's objective in creating the trans-Tasman therapeutic products authority appears to have been two-fold: first, the harmonisation of Australian and New Zealand law in medicines regulation and, secondly, the introduction of stricter safety guidelines for products capable of being used as medicines. Both objectives are legitimate. Even claimant witnesses accepted that effective safety controls are required for the sale and export of rongoa products even if there is disagreement about what the standards should be.

From the claimants' side, they argued that there was a Treaty right to deal with rongoa Māori as Māori wished. They argued forcefully that it was wrong in principle and practice for people who were not practitioners of rongoa Māori and who were external to the Māori world to impose rules on practitioners. This, they argued, would be the effect of ANZTPA. They argued that such people were ignorant of the cultural significance of the activity and of its technical practice. They complained that none of the members of the authority or any of its expert advisory committees was Māori or knowledgeable in rongoa Māori. Again, this interest claimed by Māori appeared to us to be legitimate and certainly well within the guarantee of tino rangatiratanga contained in article 2 of the Treaty of Waitangi.

We do not consider the Crown and claimant objectives to be necessarily in conflict. It is possible to protect the legitimate Māori expectation of a significant say in the regulation of traditional Māori products while at the same time ensuring the safety of those products and even the harmonisation of trans-Tasman standards. These objectives are not inherently in tension.

4.3 The prejudice is in the details

In our view, it is not possible to characterise the structure of the new regime as inherently prejudicial to the Māori interest. We do not on the other hand accept that the analysis of prejudice begins and ends at whether Māori rongoa practitioners lose ground from the status quo exemptions under the Medicines Act. There are clear arguments that the ad hoc exemption for small-scale, home-based dispensing of rongoa does not discharge the Crown's Treaty obligations to rongoa producers and practitioners. But the level of prejudice to the Māori interest arising from the regime falls to be determined in the details of the regime. It will depend on the structure of the administration and interpretation rules and the detailed wording of the medicine rules. It will depend upon whether the agency and authority make real provision for Māori participation in decision-making, not just at the level of mere consultation but in participation at board level and on expert committees.

On our reading of the ANZTPA agreement, an expert advisory committee on rongoa production, dispensing, and sale is not precluded. Nor is the inclusion of one or more rongoa experts at agency or authority level.

We are, or should be, past the stage where Māori are mere consultees in a law-making process carried out by non-Māori officials and politicians, at least when it comes to a subject as significant to Māori as rongoa Māori. We include within the ambit of this phrase not just the traditional patient-by-patient dispensing of rongoa but also the commercial development of it – whatever the scale of that development. We were particularly struck by the number of non-Māori commercial operators in the area of herbal remedies who were unanimous in their view that traditional Māori medicine is likely to be the next big thing in therapeutic developments in New Zealand. Those same witnesses were equally unanimous that Māori ought to have a significant stake in that development. The conceptualisation of the Māori or Treaty interest as an interest to be consulted upon by a largely or exclusively non-Māori officialdom belongs to another generation. In the twenty-first century, Māori and government are increasingly comfortable with the expression of rangatiratanga through shared Māori–Crown decision-making. This can be seen in the Parliament itself, in the Cabinet, in environmental and fisheries regulation, to name but a few of the many examples of which we are aware. The harmonisation of Crown and Māori objectives in respect of the regulation of therapeutic products must lead us inevitably to a similar paradigm.

In summary, we consider that:

- (a) Crown and Māori objectives in respect of the regulation of rongoa Māori are amply capable of harmonisation;
- (b) the ANZTPA agreement does not appear to pre-empt that outcome;
- (c) the draft rules in respect of medicines on the one hand, and administration and interpretation on the other, are where the possibility of shared decision-making in respect of rongoa Māori can be realised; and
- (d) it is clear that the draft rules are not a final product but rather a work in progress at this stage.

4.4 Next steps

It follows that we are not satisfied that the claimants have an arguable case for irreversible prejudice as a result of the introduction of the legislation. On the contrary, we consider that there are reasonable and realistic alternatives to delaying the legislation. In particular, as we have said, there is no inherent conflict between the objective of the duly elected government to introduce the ANZTPA regime and the objective of Māori to have a significant say in the regulation of rongoa Māori, including the commercial development. This must include not just informal dispensing but also the commercial development of rongoa Māori as a product or service.

We conclude therefore that there remains yet a significant area for dialogue and agreement between the parties, provided each approaches the dialogue in good faith, with an open mind and willingness to compromise. It is imperative therefore that the Crown and claimants agree a proper process of consultation to find that common ground. Consultation should be directed at:

- (a) a proper exemption for traditional Māori practices from the regime as currently provided;
- (b) proper parameters for the regulation of commercial rongoa products and services; and
- (c) comprehensive Māori involvement in the regulation of all aspects of rongoa practice, from traditional dispensing to retail and export of products and services.

The consultation process should involve Crown acceptance of the obligation to fairly resource Māori participation in the discussion, including a reasonable contribution to the costs of experts where necessary. But we caution that must not be seen as an open cheque-book. The consultation process must not be allowed to become the point. Since preliminary issues of this nature can sometimes provide unnecessary snags in finding common ground, we reserve leave for any party to refer an issue of funding or procedural behaviour for consideration by the Tribunal if it will assist the parties in getting to the crux of their discussion.

While there is no question in our view of the good faith of either side up until this point,

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there is still a significant gap to be closed. We agree with the Crown, for example, that a two-year process of consultation is far too long. It represents too large a fetter on the right of a duly elected government to pursue legitimate policy objectives. We would understand why, when faced with such a proposal for consultation, officials might reach the view that Māori lack a real-world understanding of public policy and the legislative process. On the other hand, given the clear indications provided in our interim report of 8 September 2006,* we think the Crown's efforts to establish dialogue were disappointing. Only one meeting was held with the claimants, and then at relatively late notice. From a claimant perspective, it invites the conclusion that the consultation process is little more than procedural damage control. To reiterate principles established often elsewhere, the engagement must be genuine, open minded, and aimed at solving the problem rather than going through the motions.

As with all good consultation processes, the first step should be to design the process itself and its objectives. We invite the parties to do this urgently. We reiterate our offer made earlier, and taken up on the Crown's side, to facilitate such discussion if it would assist.

The registrar is to send a copy of this direction to all those on the notification list for the Wai 262 flora and fauna inquiry.

Dated at Wellington this 3rd day of October 2006



Chief Judge J V Williams
Presiding officer for the coram
Waitangi Tribunal



* Waitangi Tribunal, *The Interim Report of the Waitangi Tribunal in Respect of the ANZTPA Regime* (Wellington: Legislation Direct, 2006)

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