



Drug regulator collapse dents patient hopes

Adam Cresswell
Health editor

THE COLLAPSE of plans to create a single trans-Tasman drug regulator has been greeted with dismay by consumer groups, who had been hoping the new body would prove more “user-friendly” than the existing watchdog and would be more transparent about thinking behind its decisions.

The proposed Australia New Zealand Therapeutic Products Authority, or ANZTPA for short, was shelved by the New Zealand Government last week when Wellington announced it did not have the numbers in Parliament to pass the required legislation.

Years in the planning, ANZTPA was intended to replace the Therapeutic Goods Administration in Canberra and New Zealand’s Medsafe, to take over the job of assessing the safety claims of pharmaceutical and herbal drugs and medical devices. It had a chequered history even in its development, missing two start dates after originally being intended to start operations this month.

However, the complementary medicines lobby in New Zealand had fought a long campaign to oppose the harmonisation, claiming that it would force herbal medicines sold in New Zealand to comply with the tougher rules in force in Australia.

Accepting the decision, Parliamentary Secretary for Health Senator Brett Mason said the Australian Government “understands the difficult political situation” faced by the New Zealand Government, “and in these circumstances has agreed that postponing negotiations on the joint agency is a sensible course of action.”

“The Australian Government remains committed to a world-class regulatory scheme for therapeutic goods and it will now proceed in a way that allows both countries to explore other options for harmonisation in the interim,” he said.

The Government said Australia’s existing regulator, the Therapeutic Goods Administration, would “continue to operate under its existing full-cost recovery arrangements”, which ensure that the cost of the TGA’s operations are met from fees paid by drug manufacturers.

However, the TGA has often been criticised within Australia for a lack of transparency, as well as a perceived lack of independence from the drug industry, and critics had hoped the

transition to ANZTPA would prove an opportunity to fix these flaws.

The consumer organisation Choice said it wanted “a more independent and transparent regulator that makes information about its decisions available to the public”.

“We had been meeting with the TGA regularly to advocate for the establishment of a consumer consultative committee under ANZTPA, as well as a more ‘consumer-friendly’ website,” a spokeswoman said.

“We hope that the decision not to introduce a joint regulatory system will not affect the TGA’s efforts to become more independent and transparent. Consumers deserve to know why some drugs are approved and others are not, irrespective of the name and boundaries of the regulator.”

However, another medicines policy expert — Thomas Faunce, a senior lecturer in law and medicine at the Australian National University — greeted the collapse of the plans as a “good thing” for New Zealand. Faunce said the “stakeholder consultation” sessions held by the Australian government to shape the development of ANZTPA were “a sham and a farce” were designed to accept only department and drug industry views.

And he claimed that had the joint regulator gone ahead, it would have forced New Zealand to also accept the obligations foisted on Australia as part of the free-trade agreement with the US that came into effect in 2005.

Under these obligations, generic companies were required to notify drug manufacturers of their intention to enter the market with a low-cost copy of a branded drug — a measure that promoted “evergreening” of big-brand medicines because their makers would then have time to mount defensive action, Faunce said.

“If I was a generic drug manufacturer I would be looking to up sticks now and relocate to New Zealand . . . where I didn’t have to disclose to the (big-brand) manufacturer that I was aiming to enter the market.”

Representative groups for the pharmaceutical giants in both Australia and New Zealand said they were disappointed with the postponement of ANZTPA. Medicines Australia said it was a “missed opportunity” but hoped simplification of Australia’s regulatory arrangements would still continue.