TRANSTASMAN AGENCY FOR MEDICINES ABOUT MUCH MORE THAN PILLS

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HERE'S a way to get up an Aussie nose: Junk the proposed joint therapeutics agency. Which would probably get up our own nose by setting back progress towards the single economic market (SEM).

Health ministers _ on this side Annette King _ agreed in 2003 to set up the therapeutics agency as a supranational regulator of medicines in both countries, modelled in part on Food Standards Australia New Zealand (FSANZ) which looks after food safety.

But there is a real possibility Parliament here won't ratify the deal. This would go down badly in Canberra and the state capitals.

Therapeutics are essentially medicinal drugs _ but not just the ones doctors prescribe. The agency is also intended to cover alternative medicines, over-the-counter medicines and food supplements, as Australia's Therapeutics Goods Administration (TGA) has done but our Medsafe has not.

Some can cause harm. A case in point was some Pan Pharmaceuticals drugs in 2003. TGA issued a recall.
Most are not harmful _ quite the opposite. But many are produced and sold not by the cash-rich pharmaceutical giants, which can jump expensive regulatory hurdles, but by small, cash-poor operators who cannot afford the cost and, therefore, whose products, the Greens worry, will not be available.

Health-food shops have organised resistance. This has impressed New Zealand First and elements of the National Party.
Maori groups oppose the agency for fear that traditional Maori medicines will be barred on safety or registration cost grounds. That is a factor in Maori Party thinking.

There is also a "sovereignty" issue for some parties, notably the Greens, who opposed FSANZ partly on this ground.
So there is no majority for the enabling legislation which has yet to be tabled. The Australians are getting restless. Detailed rules are supposed to be finalised by January.

The joint agency would have several advantages for both countries.
It would provide a wider pool of technical experts to assess drugs _ or assess and apply decisions of the European and United States drug agencies _ and gives Australasia more credibility and influence in international regulatory circles.

A joint agency would spread the cost across two jurisdictions. It would create a single Australasian market for drugs and make it more likely the big drug companies will bother to register them, especially for the tiny New Zealand market.

Without a joint agency, all this will fall on Medsafe, which is struggling with a backlog of applications for approval _ three years, compared with 15 months in Australia, according to the Registered Medicines Industry (RMI), which represents the major drug companies.

Medsafe has recently jacked up its approval fee to a level the RMI says will deter companies from applying for some medicines, since less than a quarter of the drugs Medsafe does approve each year are subsidised by Pharmac.

But there is a bigger issue: The seamless "single economic market" in Australasia.
The Australians took on board New Zealand disquiet at the Australian dominance of FSANZ's governing bodies. The therapeutics agency would give the two countries equal weight.

This would be a valuable pointer to the governance of future joint agencies.
But if this one fails, Australia's interest in building more joint agencies may well wane. Why bother with a cantankerous junior partner?

Good thing, critics would say. But the damage would probably be much wider.
New Zealand has far more to gain from progress towards the SEM than Australia because each gain improves New Zealand businesses' access to a far bigger market while the reverse is true for Australian firms.

So for 17 years since the SEM was first mooted, it has been an uphill struggle for New Zealand to get the Australians to bother about it. Progress has been slow and bumpy. Australia has bigger fish to fry.

Failure to ratify the therapeutics deal would give more weight to officials in Canberra who resent spending time on the transtasman tiddler. This implication is well understood at high levels in the Beehive and I understand the point has also been made by Liberal ministers in Australia to their National counterparts here.

National has had three principal concerns _ apart from not being consulted by King as she negotiated the deal in the first place. The concerns are the generally high compliance costs in meeting an Australian-type highly prescriptive regime, the desirability of low-cost approvals for complementary medicines and more scope for simply adopting European and/or American approvals.

So quite a lot rides on Food Safety Minister King's indelicate negotiations with other parties.
In part this rests on what changes she can yet get from Australia _ and there is apparently some room for manoeuvre. But it also depends on either New Zealand First playing poodle or the National Party _ notably foreign affairs spokesman Murray McCully (not habitually a proponent of the long-term national interest) and trade spokesman Tim Groser (long habituated to long-range national interest thinking on trade) _ putting the transtasman relationship ahead of domestic sectional political gain at home and taking their caucus with them.

But the therapeutics muddle holds another lesson: MMP has changed the rules. Trade negotiations need the main opposition party on side.

Labour was onside when CER was negotiated with Australia in the first place. It might usefully have paid attention to history in its therapeutics deal.

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