

## **Brief Overview of Proposal to Establish Joint Trans-Tasman Therapeutic Goods Agency**

In New Zealand dietary supplements are presently controlled under the Dietary Supplements Regulations 1985 that are made under the Food Act 1981. It is generally agreed that this is neither an effective nor appropriate form of regulation and both Industry and Government have been in agreement for some time that it is an area that needs review. As late as 2000 it was the stated intention of the Government to regulate dietary supplements by way of their own specific legislation setting up an appropriate risk based regime. Broadly speaking the Industry supported those proposals and they had come about as a result of an ongoing period of consultation with the Industry in New Zealand.

In 2002 the Ministry of Health put out a Discussion Document in which it set out that its intentions had changed and that it now wished to establish an agency which would regulate all therapeutic products, both pharmaceutical and natural health products for both countries. The proposed agency seemed, for all intents and purposes, to be an extension of the existing Australian Therapeutic Goods Agency (TGA) to cover both countries. The TGA website in fact announced that its intention was to extend its reach to both Australia and New Zealand and certainly the proposal appeared to support this in effect if not in name.

As a result of intense Industry lobbying, primarily carried out by the New Zealand Health Trust, and as a result of the 30,000 strong Sue Kedgley petition presented to Government, Industry succeeded in having this proposal forwarded to the Health Select Committee for its consideration.

The Committee, made up of five Government Members and six non-Government Members, spent the majority of 2003 hearing evidence from affected parties including representations from MedSafe and the TGA and a large number of industry submitters. For its part the New Zealand Health Trust brought evidence from a Constitutional Law Expert, a Senior Economist, a Consultant working under the current TGA regime in Australia and a number of producers of small run dietary supplements, all of which showed that the proposal would be damaging to New Zealand businesses and consumers. The net effect of the proposal would be to push compliance costs for New Zealand businesses up to levels that many would not be able to sustain resulting in the closing down of many businesses and the loss of many current lines of products. The products that remained were anticipated to have substantially increased prices. In addition the constitutional and national sovereignty difficulties of giving the power to regulate a New Zealand industry to an Australian based body were found to be particularly worrying and unprecedented.

In December 2003 the Health Minister Annette King, in response to a question in Parliament announced that she was to sign the Treaty with Australia committing to the establishment of the Joint Agency even though at the time the Select Committee had not released its report into the proposal. This was seen by most as a blatant disregard for due process of Parliament and a slap in the face for those who had spent considerable time and money setting out their evidence for the Select Committee. Not more than a few days after the Minister's announcement the Select Committee did indeed release its report which unanimously condemned the Government's proposal as being detrimental to the interests of New Zealand both for its businesses and for its consumers.

Unprecedented cross-party opposition was achieved and National, ACT, the Greens, United Future and NZ First all joined together to give a Press Conference pointing out that the Governments actions were in clear contravention of the Select Committee's recommendations and should not proceed.

Nevertheless on 10 December 2003 Annette King signed the Treaty with the Australian Government committing the Government to proceed with the establishment of the joint agency.

This Treaty was then itself referred back to the Health Select Committee for consideration and once more interested stakeholders, including the New Zealand Health Trust, spent considerable time and effort making submissions to the Committee on the effect of the Treaty and explaining the extent to which the same was incompatible with the recommendations of the first Health Select Committee report.

In June 2004 the Health Select Committee released its report into the Treaty and found that the Treaty should not be accepted by Parliament as it did not satisfy the recommendations of the Committee in its earlier report. The Committee found that unless significant safeguards could be built into the legislation the joint agency should not proceed. The New Zealand Health Trust is clear in its view that those recommendations are incompatible with the wording of the Treaty and as a result the Government will be unable to provide legislation which satisfies its obligations under the Treaty and meets the requirements of the Health Select Committee Report.

It is important to note that although the Treaty has been signed with Australia, this is no more than an obligation between the two Governments to proceed with this line. It does not bind New Zealand, nor has it made the joint agency law in this country. For those things to occur legislation will need to be put before the New Zealand Parliament and accepted by a majority of the Members of Parliament and this has not yet occurred. Equally it is important to note that our current Government is a minority Government and cannot pass this or any other legislation on its own without the support of at least one of the minority parties. Given the total rejection of this proposal by all other parties to date it is clear that the Government still has considerable obstacles before it could have such legislation passed. The establishment of this agency then is a long way from certain. Despite this the Ministry of Health has been proceeding with the establishment of the agency as if it was a given. Numerous advertisements have appeared in major New Zealand newspapers seeking staff for this agency and significant taxpayers' funds have been spent developing the business that the Government hopes will become the New Zealand part of the joint agency. To those who have been opposing the agency, the Government is seeming to present a picture of fait accompli in the hope that the opposition would fall by the way side.

## What Next?

As set out above, the joint agency will be devastating for the New Zealand Health Products Industry. Businesses will close, jobs will be lost, products will be limited and the price for the products that remain will increase significantly. Australian Government papers into this proposal record that the Australian businesses will receive a competitive advantage over their New Zealand counterparts. We can expect to see more Australian made products on our shelves and far fewer New Zealand made products. Equally we know that under the existing Australian regime many products New Zealanders currently rely on will be unavailable.

Despite all indications from the Government to the contrary, the joint agency is not yet a reality. The legislation must be passed by a majority of the Members of Parliament and on the current numbers the Government does not have the necessary support to achieve this. As long as the New Zealand industry and consumers continue to show their opposition to the proposals and continue to put pressure on the opposition parties to vote against these proposals there is every chance that the TGA will be defeated.

Given the way Parliament works, the Government are the only ones who know when this legislation will be presented to Parliament and so the industry needs to stay continually alert and develop a strong data-base of contacts so that when the legislation is presented to Parliament everyone can be contacted quickly and mobilized to voice their concerns.

The New Zealand Health Trust on its own website, [www.nzhealthtrust.co.nz](http://www.nzhealthtrust.co.nz), have compiled a list of all the documents relevant to the history of this proposal so that anyone who is interested can read further as to the detail of the proposal and the difficulties with it. The website also contains a useful template for contacting your MP to express opposition and a newsletter forum which provides an excellent method of building the necessary industry contact database. We would encourage you to visit this site, read the information about the proposal, register your details in the newsletter and contact your MP to express your opposition.

The industry must be clear that this proposal will be exceedingly damaging to the New Zealand Natural Health Products Industry and we stand a very good chance of defeating it as long as we continue to act collectively and make our wishes known.