

FURTHER SUBMISSION
TO THE HEALTH SELECT COMMITTEE

IN RESPONSE TO THE PRESENTATION BY MEDSAFE
AND THE THERAPEUTIC GOODS ADMINISTRATION

**INQUIRY INTO THE REGULATION OF
DIETARY SUPPLEMENTS**

PRESENTED BY THE NEW ZEALAND HEALTH TRUST

[MEMBER OF THE DIETARY SUPPLEMENTS CONSULTATIVE GROUP]

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Executive summary

- Dr Keller's presentation, whilst interesting, was in the end of little relevance to the issues at hand.
- The presentation showed that the EU in fact supports the treatment of vitamins and minerals as foods NOT medicines as is proposed under the Joint Agency ("JTA").
- Even in the European Union regulation between member states has only gone so far as mutual recognition rather than delegated legislation from each of the sovereign states to one single body as proposed here.
- The presentation made it clear once and for all that the JTA proposal is essentially joining with the TGA with a few "tweaks" to the system.
- The only response from the TGA as to their excessive cost burden on industry was to claim that they are working on it.
- The TGA presentation highlighted the dissention within Australia as to their own system.
- Medsafe accepted that they are continuing to work toward the implementation of the JTA notwithstanding the level of opposition toward it as expressed to the Committee. This raises serious concerns as to their impartiality as an assessor of the validity of those concerns and of the alternative models available to them.
- The Medsafe presentation made it clear that most of the detail of the proposal was still not formulated making it impossible for submitters to properly assess and comment on the exact nature of the system.
- What is proposed is the handing over of the power to make all rules to a body over which New Zealand Stakeholders will have almost no real ability to influence.
- Alternative models are available and should be properly and independently considered and assessed next to the JTA option, which has yet to occur.

Comments on the presentation of Dr Konstanin Keller – European Medicines Evaluation Agency

- This was an interesting presentation on the German and EU system however it must be remembered that the EU system is considerably different to that currently used either in Australia or New Zealand and was not relevant to present inquiry for following reasons:
 - (i) Whatever the merits or otherwise of particular elements of the European system it has no relevance to the system proposed in which the details have not yet been prescribed. There is no assurance that any of the desirable elements of the EU system will be included in the proposed JTA system.
 - (ii) In the EU, Dr Keller advised that natural medicines are subsidized in the same way as pharmaceutical medicines. The cost burden on those industries of being treated as drugs is therefore substantially off set in a way that is not proposed by the JTA. It is inappropriate to compare one element of their system with what is suggested here without recognizing the significant wider differences between the systems.
 - (iii) Dr Keller said that he was not able to talk to the regulatory cost burden of the EU system on industry which is acknowledged to be one of the key elements in assessing the system proposed. The system cannot be assessed without full instruction as to the cost burden it imposes.
 - (iv) In the EU, whilst herbal products are treated as medicines, vitamins and minerals are considered foods. That is a significant difference to the system proposed. Vitamins and minerals are arguably the biggest component parts of the dietary supplement industry. If these are not treated in the EU as medicines but foods then one must question whether Dr Keller's evidence really supports the JTA system which would instead take the opposite approach and treat vitamins and minerals as medicines.

- Dr Keller acknowledged that whilst innovations are welcome in principle, in reality they are not often achieved. This admission arose during questioning from the committee as to whether the necessity for clinical trials for new products tended to stifle innovation. The response indicates clearly that that is indeed the case.

- It was most interesting to note that even in the closely allied European Union where issues of harmonization have been far more advanced than under CER, mutual recognition between the sovereign states were as far as they have been prepared to go. Dr Keller addressed this point and noted that the member states had however an overriding body to settle disputes. Once again, whilst this is interesting, that is not what is proposed here and so cannot be taken as giving any support to the JTA proposal.

Comments on the presentation of Dr Fiona Cummings – Australian Therapeutic Goods Administration

- Firstly it was of considerable interest that the TGA were invited to address the Committee given that Medsafe in their own submission at page 99 indicated that submitters were wrong in assuming that the proposal was for NZ to adopt the Australian model. Medsafe stated that the TGA was not what was being proposed here and there were to be “important differences”. Submitters, on the whole have never believed nor accepted that the proposed JTA was anything but the TGA by any other name. The fact that the TGA website openly proclaims that it will be joining with New Zealand as the regulator of Trans Tasman therapeutic goods further justifies this view.
- Despite the comments by Dr Cummings that complementary medicines are treated distinctly from pharmaceutical medicines under the TGA, what must be borne in mind is that in Australia they remain a subset of medicines and are treated as such. The Australian system is in no way the three tier system talked of and used in other jurisdictions where dietary supplements are treated as a separate group, distinct from both medicines and foods. This three tier system is what the industry advocates be adopted in New Zealand. Even Dr Keller explained how the EU has seen fit to leave a large portion of what we describe as dietary supplements in the food category as being more appropriate there than included as medicines.
- _____ Dr Cummings noted that only 2 of the Australian states have adopted legislation supporting the TGA. Whilst Dr Cummings said that it was planned in the remaining states it does raise the question of why this is still the case more than 10 years after the TGA was originally introduced.
- _____ Dr Cummings mentioned some of the costs involved in listing a dietary supplement, namely approximately \$465 to list and a further \$505 for annual fees. What however was not mentioned were the extensive consultants costs that have become a necessary part of the registration process in Australia, the further fees if any part of the application is rejected, the labeling and advertising approval costs or the large upfront costs for a manufacturer to buy the necessary software to use the TGA’s electronic lodgment facility. The huge total cost burden the TGA places on the dietary supplements industry in Australia has already been detailed to the Committee by several submitters and should not be discounted by the glossing over of these costs by Dr Cummings.

- In response to questioning about the GMP (good manufacturing practice) code, Dr Cummings answered that the same code was used for all therapeutic products but was applied differently for different types of products, e.g. dietary supplements. We would suggest that not only does this create unnecessary cost for dietary supplements based on an actual risk assessment, but also an unacceptable level of uncertainty given that the potential exists for insistence with the strict wording of the code.

Comments on the presentation by Medsafe

- Medsafe testified to the Committee two things very clearly which must be borne in mind:
 - (i) The system that they are proposing through the JTA is now described by them as being essentially the TGA, with a few “tweaks”. Their comments therefore that criticisms directed toward the TGA were irrelevant must be reconsidered.
 - (ii) Medsafe have selected the JTA as their preferred option. Despite the Committee’s inquiry they are continuing to work toward the implementation of the JTA. This makes it clear that they can in no way be regarded as or relied on as an independent, objective assessor of all options. The dietary supplements industry has presented alternative regulatory models to Medsafe however is concerned that their pre determined selection of the JTA means that such models are not being given due and appropriate consideration.
- Medsafe testified that the JTA model was shown by the NZIER report as being a cheaper regulatory model than running our own NZ based system. In fact the NZIER report concluded clearly at page vi and vii of its executive summary that actual compliance costs would rise under the JTA proposal which will affect profitability where these costs can’t be passed to consumers. The report further states that whilst some small benefit appeared in respect of the pharmaceutical industry, the proposal carried with it a cost detriment to the dietary supplements industry. Given that this inquiry is considering the application of the JTA to dietary supplements rather than for medicines as a whole, it is misleading then for Medsafe to state that the NZIER report supported this proposal from a cost benefit perspective.
- In answer to the Committee’s questions, Medsafe testified that they were still looking into the compliance cost of the proposal on the complementary health products sector. In our submission these investigations should have been completed by now, before the industry

was asked to respond to the proposal and before Government considered accepting the same.

- Medsafe indicated that on its own analysis the cost burden on the industry of the JTA was likely to average around 2% of turnover. This fails to deal with the fact that profit in such firms is often around 6-8% of turnover meaning that these cost would therefore consume as much as one third of the profit of these companies. It is the cost as a percentage of profit that determines the on going viability of firms, not as compared to turnover.
- When questioned about the governance issues that arise from the proposal, Medsafe acknowledged that allowing both governments to have proper voice was “quite a challenge”. Further they stated that the final policy was as yet developed as to the details of how that would work. This raises the question of how submitters can be expected to properly raise or contest the perceived inadequacies of the system when the details of the same remain unknown.

Conclusion and general comment

The proposal in front of select committee is not one of detail of how the system will work but rather one to simply give the power to set that detail to the new JTA, which we now know to be the TGA with “a few tweaks”. As such we cannot compare this new system to other systems around the world as we do not yet know conclusively just how it will be designed. The questions that must be asked instead is whether it is appropriate to give that wide ranging power to this new body and what effective redress we will have should we, as a country and or as the industry, be dissatisfied with the way the power is used.

In our submission the power to be given is too wide ranging and gives too much control and discretion to this new agency.

We know from evidence presented to the Committee from Philip Donnelly & Associates, Economists, David Tan & Associates, TGA Consultants, from the NZIER report and from existing users of the TGA system, that the cost burden on the dietary supplements industry is likely to be not just significant but such as may send many in the industry out of business.

It is inappropriate and against natural justice to give such wide ranging powers to an off shore official whose primary task is to regulate and control pharmaceutical products. Medsafe claimed this was no different than the powers held by the CEO of Civil Aviation however the proposal to include dietary supplements into the JTA is like authorising that official to also then regulate the use of trains on the grounds that they are all modes of transport and then locating him in Canberra to make it cheaper.

Other regulatory models are available which can meet all requirements as to the protection of the public without taking the undesirable step of forcibly including dietary supplements in the inappropriate category of medicines and without imposing

such a high cost burden on the industry. Until such time as all the models are properly detailed and impartially considered against each other then we suggest the abdication of the power to regulate dietary supplements to the JTA must be avoided.