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Copy of letter to:

Senior government officials
Stewart Jessamine (Ministry of Health)
Susan Martindale (Ministry of Health)
Geoff Sanderson (Ministry of Economic Development)
Barbara Bridges (Ministry of Foreign Affairs & Trade)
Bob Boyd (Ministry of Health)
Unknown Official (since identified as Cathryn Ashley-Jones – Prime Minister's Department)

Copied to respective Ministers of the Crown

The Hon Annette King (Health)
The Hon Jim Anderton (Economic Development)
The Hon Phil Goff (Foreign Affairs & Trade)
The Hon Helen Clark (Prime Minister)

3 November 2000

Healthcare and Therapeutic Products Bill

We understand that progress is being made with the drafting of this Act. While the respective Ministry representatives involved should be well aware of the industry viewpoint, it is probably an appropriate time to remind the drafters of the rationale and consensus which has been arrived at by industry, after much consultation here in New Zealand and with our sister body in Australia, the Complementary Healthcare Council.

1. Proposed Healthcare and Therapeutic Products Bill

a) The NNFA has long held that complementary healthcare products should be regulated commensurate with their extremely safe profile evidenced by very low adverse reaction rates in clinical studies, lack of significant adverse reaction reports and a very long history of safe use.

b) Dietary supplements are not pharmaceutical drugs and should not be regulated as such.

c) NNFA is committed to ensuring that both distributors and consumers have unrestricted access to high quality and safe complementary healthcare products.

d) Consumers have the right to know the purpose for which dietary supplements are intended – present legislation denies them this information.

e) As such, we support the proposed Healthcare and Therapeutic Products Bill which gives complementary healthcare products equal status to pharmaceutical drugs, but recognises their inherently safer profile.

f) NNFA insists that evidence based risk analysis undergird the regulation of safety of dietary supplement products. This includes the use of both scientific evidence and evidence of safe history of use.

g) NNFA has agreed to manufacturers/suppliers being licensed. We have agreed to this on the basis that licensing is not seen as a revenue earner, but rather as the equivalent of a dog license – you need one to be in business.

h) NNFA has agreed to a simple product notification system which would require information limited to the manufacturers name and importers name if imported, address, product name and actives, and acknowledgement of Good Manufacturing Practice (GMP).

i) NNFA has agreed to appropriate GMP.

j) The Ministry of Health has agreed that the existing philosophy of negative listing be retained. This means that products are only able to be restricted if there are scientifically valid safety issues.

k) We note in an "Office of the Minister of Health" attachment to the Director General of Health's report (AD10-01-1-10, 21 Jan 2000) that 'fees will be applied for cost recover'. This has not been discussed with industry and will require a great deal of thought, especially as our industry is not subsidised by the government as is the pharmaceutical industry. If the Australian system was applied to New Zealand it would clearly force most of our small distributors out of the market.

l) The present direction of trans-Tasman Harmonisation being driven by TGA is incompatible with New Zealand industry and consumers views regarding freedom of choice.

2. Trans-Tasman Harmonisation

a) You will note that The National Nutritional Foods Association of New Zealand has been actively pursuing satisfactory progress of Trans-Tasman Harmonisation (TTH) of complementary healthcare products since May 1998.

b) Unfortunately, our experiences have not convinced us that the Australian Therapeutic Goods Administration shares our objectives. They appear to want to force their present regulatory system upon New Zealand industry. This is completely unacceptable to us because the Australian system is prescriptive, costly, restrictive and inappropriate. Furthermore, New Zealand industry is not happy with the performance or methodology of the TGA (or ANZFA for that matter) regulatory approach to a number of issues including the bee products fiasco.

c) Trans-Tasman Harmonisation is not about a dominant partner imposing its paradigm on the other but rather, is intended to develop solutions that enable free trade of safe and good quality products.

d) The much-vaunted Australian reforms have not worked, and have in fact increased industry costs and lead to more prescriptive codes of practice. Australian industry is itself very dissatisfied.

e) NNFA simply rejects the Australian TGA's prescriptive, restrictive and expensive model as being suitable for trans-Tasman Harmonisation. It is an effective non-tariff trade barrier.

f) Industry on both sides of the Tasman believe that the Canadian model developed by the Canadian Parliament's Standing Committee and implemented by their government should be used as a basis for future trans-Tasman Harmonisation.

More recently, we understand Graham Peachey, Assistant Secretary, Regulatory Reform Task Force in Canberra has been asked to consult on a possible framework for a joint Australia New Zealand office.

The following are extracts from the CHC response to the Consultation paper on a possible framework for a joint trans-Tasman agency to regulate therapeutic goods:

The CHC appreciates the opportunity to comment on the proposed framework for a joint Australia New Zealand office put forward by the "Regulatory Reform Task Force".

CHC Position

The CHC (in line with the NZ Dietary Supplements industry), supports harmonisation of <u>appropriate</u> regulation of Complementary Healthcare products, including a joint office to regulate Complementary Healthcare products <u>separate</u> from pharmaceutical and prescription medicines. Neither industry will support any proposals to continue regulation of these products in a pharmaceutical paradigm.

Experience has demonstrated clearly that regulation of these products under the Therapeutic Goods Act 1989 and Regulations is prescriptive, costly, restrictive and inappropriate. It does not allow consumers access to a wide range of high quality, low risk products, nor to good factual information about those products to assist in making an informed choice. It does not respect consumers' freedom of choice nor their philosophical and cultural diversity. Further it does not protect public health and safety as it encourages consumers to access product of unknown quality and safety by mail order via the internet when products that are freely available in other comparable countries cannot be obtained domestically.

Regulation of Complementary Healthcare products in a pharmaceutical environment is out of step with other comparable countries, rather than leading the rest of the world as claimed by the TGA. It focuses on disease and illness instead of enhancing health and wellness.

The various regulatory reforms that have been offered to the Complementary Healthcare industry in Australia over the last 5 years have not delivered the minimal effective regulation espoused in the COAG principles, nor have they delivered the 'separateness' within the TGA that was promised.

General Comment
The paper perpetuates the difficulties that emanate from a regulatory system that covers both pharmaceutical and Complementary Healthcare products, by lack of recognition of the inherent differences.

Essential Principles
The principles proposed to underpin any joint agency for regulating Complementary Healthcare products are in general supported subject to the following comments:

1. *The Australian government's support for export should be reflected in the principles by changing the wording to 'facilitate and promote the export of complementary healthcare products'.*
2. *Addition of another principle in line with the objectives of the ANZFA Act to state "promote fair trade and commerce in Complementary Healthcare products".*
3. *Funding of any joint agency should cover only those activities that provide services to the industry, with public interest responsibilities funded by the government.*
4. *Regulation of Complementary Healthcare products must be a co-regulatory model, with industry and regulators working in partnership.*

Proposed Models
The CHC strongly supports a joint agency as the preferred model, but separate from pharmaceutical and prescription medicines – that is, established under separate legislation. The CHC will not support the model as proposed, but is keen to work on a similar model for complementary healthcare products.

Examples of activities proposed for the Joint Agency Model do not include:
- *Approval of new ingredients, including access control where appropriate*
- *Adverse event reporting*

The other models proposed are considered to introduce even more complexity and confusion which will result in onerous and unnecessary regulation, lengthy delays, increase costs and uncertainty, and are not seen as capable of achieving a common or even harmonised market.

Transitional Issues
Does not provide for grandfathering of substances already on the market in New Zealand.

CHC Position
The CHC would support a single joint agency to develop policy in a partnership arrangement with the Australian and New Zealand complementary healthcare industries subject to the following:

- *Office and regulation to be independent from both food and pharmaceutical medicines.*
- *Office of CHP to be staffed by persons with a knowledge and understanding of complementary healthcare, and headed by a qualified natural healthcare professional.*
- *Co-regulatory approach, including contracting services out to independent bodies.*
- *Funding of only those activities that provide services to the industry.*
- *Minimal effective regulation reflecting the low risk nature of these products and the different philosophy and cultural diversity of complementary healthcare.*
- *A transparent and accountable regulatory system.*
- *Consistent with the regulatory approach of other comparable countries.*
- *Grandfathering of all substances that have been freely available in New Zealand for the last two years with no known public safety problems.*
- *Appropriate GMP.*

Conclusion
The CHC fully supports appropriate regulation of CHPs and believes that there is value in a trans-Tasman common market for complementary healthcare products, regulated under an appropriate system separate from both food and medicine and administered in a co-regulatory approach by a joint office of the same standing as ANZFA and TGA.

I look forward to working with the Regulatory Task Force, and our New Zealand colleagues to develop an independent Office of Complementary Healthcare Products that will ensure consumers have freedom of choice of a wide range of low risk, high quality Complementary Healthcare products, and balanced and truthful information about those products to assist in making informed choices.

Val Johanson
Executive Director
3 August 2000

Conclusion
The government has a duty not only to minimise future compliance costs but also to assess the current regulatory burden. The benefits of any regulation should outweigh the commensurate short and long-term costs.

With potential harmonisation we have the opportunity to compare current Australian and New Zealand regulatory practice. In view of the risk profile, New Zealand's regulatory approach, while not perfect, is superior so we must at all costs ensure we do not accept the TGA model.

Yours faithfully
National Nutritional Foods Association of New Zealand
(Signed)

John Blanchard
President

Warren Sanderson
Chairman
Regulatory Affairs Sub-Committee