JOINT INDUSTRY POSITION STATEMENT

REGULATION OF THERAPEUTIC PRODUCTS IN NEW ZEALAND

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1. While the Therapeutic Products & Medicines Bill is on hold, industry is left in an unacceptable position of uncertainty. Parts I – V of the Bill should therefore be formally withdrawn or defeated.

2. Work must begin immediately on a new NZ system of regulation specific to natural health products and devices based on the recommendations of the first health select committee report into this issue.

3. New Zealand natural health regulation must be –
   - constituted under its own Act of Parliament;
   - controlled by a small stand alone body within the Ministry of Health not also tasked (directly or indirectly) with controlling pharmaceuticals, staffed by those with established backgrounds in the sector (not those who routinely disparage the industry);
   - proportionate to an objective and independent risk assessment of the natural health sector based on properly corroborated data; and
   - designed in consultation with leading natural health industry and consumer groups who can demonstrate widespread public or industry endorsement and approval.

4. The NZ system of natural product regulation should contain the following basic elements:
   - A computer based product register that records all natural health products sold in New Zealand via a simple self-assessment electronic system.
   - A manufacturing procedures (GMP) system, appropriate to the quality risk posed by the products, and based on qualified and robust systems and procedures.
   - A 'negative list' of ingredients or products that are banned or controlled because they do not meet acceptable international standards. The negative list should be maintained on an online database so the health practitioners and health authorities are well informed.
   - A system of random testing of products to ensure compliance and that products are true to label.
   - An advertising code specific for NHPs, administered by a co-regulatory body of industry, consumers and regulators – which will include a complaint resolution panel.
   - A Guideline on Levels of Evidence that requires industry to hold evidence to support claims but encourages industry to provide consumers with balanced information on the use and benefits of natural healthcare products.
   - An Expert Advisory Committee comprising persons with expertise and knowledge of natural healthcare.

5. If the Therapeutic Products and Medicines Bill is brought back to the house then the legislation must be amended to specifically exclude the joint agency from having any jurisdiction over natural health products and devices (including those with a natural health component) with the definitions of these industries to be agreed following proper consultation.

6. The following will not be accepted:
   - Any "opt in/opt out" system from a Trans Tasman agency for NZ domestic natural products.
   - A parallel NZ agency for natural products reflecting the ANZTPA rules in all but name.
   - Planned regulatory creep which would see natural products brought within a joint agency over time.
   - Regulation of natural health products under ANZTPA.
   - Regulation of natural health products under the same system as Pharmaceutical and over the counter medicines in any way.

Prepared by the NZ Health Trust, July 2007.

This position is supported and endorsed by the following businesses/organisations:

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Business/Organisation: _____ Business/Organisation: _____

_____ _____

Phone: _____ Fax: _____ Phone: _____ Fax: _____

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Name: _____ Name: _____

Signed: _____ Signed: _____

Date: _____ Date: _____

Business/Organisation: _____ Business/Organisation: _____

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Please return both pages to: Amy Adams on fax 03 377 2999;
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