

Dear Colleague,

Following the shelving of the Therapeutics Products Bill last month, the industry has been left in limbo by a Government that lacks the courage to admit its mistakes and get on with designing the purpose built NZ system that is needed for regulating natural health products.

What is needed now is for this industry to come together to show that despite the picture the Government is trying to paint, this industry supports regulation but insists that it be sensible regulation designed around the actual risk profile of the products, which we know to be very low.

To achieve this we have written a simple position statement which we believe covers the main concerns we share and supports the recommendations of the first Health Select Committee report about what is needed for the future.

This statement has deliberately been kept "big picture" as now is not the time to get caught up in arguments over matters of detail. The aim is to demonstrate that we all agree on the key elements of the way forward and to put pressure on Government to act to this basis.

This position statement linked below already has the support of many key organisations in the sector and we would encourage those of you operating **businesses or organisations** in the natural health area to **add your voice** to this call by printing off the attachment, filling in the required details, signing it and faxing it back to Amy Adams or you can post it or use the web form.

The more businesses that endorse this Joint Industry Position Statement, the more powerful it will be and the more likely it's success. We need to show the Politicians a united & responsible front.

Amy is collating responses on behalf of the Trust and will then present the same to key political and media figures on behalf of all of those who have endorsed it.

See the reverse for details of the statement and the instructions on fax and post.

or

go to this link to submit your endorsement online. http://www.nzhealthtrust.co.nz/position_statement.php

Kind regards,

Dave Sloan

Phone 03 3519807 www.nzhealthtrust.co.nz

JOINT INDUSTRY POSITION STATEMENT REGULATION OF THERAPEUTIC PRODUCTS IN NEW ZEALAND

- 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 Parts I V of the Bill should therefore be formally withdrawn or defeated.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 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.
 - 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 those products are true to label.
 - An advertising code specific for Natural Health Products, 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:

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- 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 business:

Business/Organisation:		
Phone:	Fax:	
Email:		
Name:		
Signed:	Date:	

PLEASE PRINT CLEARLY IN BLOCK LETTERS

Please return to Amy Adams on fax: 03 377 2999 Or post to: Amy Adams, Mortlock McCormack Law, PO Box 13474, CHRISTCHURCH 8031