

## **NZORD submission to the Ministry of Health consultation on the development of a natural health products bill – May 2010**

This submission is from John Forman, executive director of NZORD, the New Zealand Organisation for Rare Disorders.

### **Introduction**

NZORD is an umbrella group set up to provide information, support and advocacy for patients and families affected by rare disorders, and to assist with the development of support groups for them. We build collaborative relationships with health professionals, health planners, researchers and industry, to improve knowledge about rare diseases, improve clinical care, and develop treatments and cures for rare diseases.

We draw your attention to past submissions we have made on complementary and alternative medicines. See [our 2007 submission](#) on the Bill (which did not proceed further) about a joint regulatory regime with Australia, and [our 2003 submission](#) to a Ministerial committee on complementary and alternative health.

This submission should be seen in the context of our support for a process for recognising the place for and wide acceptance of natural health products in our society, and providing for appropriate regulation to ensure consumers are protected from harms from such products.

However our support is qualified by concern about whether the proposed regime will provide adequate restraint on the apparently small but determined element among marketers of such products who from time to time prey upon vulnerable people with claims of significant health improvements from unproven and often very expensive products.

We think that regulation put in place must be firm enough to cope with the worst excesses of this minority element in what seems to be a generally responsible and maturing industry, as well as provide for a good level of certainty that responsible members of the industry will still be bound by rules that ensure consumer confidence in the safety of their products and validity of claims made.

Therefore issues of safety, claims, evidence, manufacturing quality, oversight, advertising, and industry ethics, need to be more robustly addressed.

## **Comments on the discussion paper**

Rather than address each question separately we have gathered our response into six key areas of interest and have referenced the relevant questions from the consultation paper in brackets.

### **1. Scope of the suggested bill and administrative matters (questions 1-5)**

In general we support the scope, purpose, principles and administration of the bill. The regulation of natural health products is something that is sorely needed in New Zealand.

We believe the structure and function of the 'consultative group' needs to be carefully considered so that it comprises appropriate representation from across the wider health sector. Specifically the views of manufacturers and importers of natural health products must be balanced by the views of those cautious about the use of natural health products for treatment of disorders, serious or otherwise. Along the same lines we believe it is essential to make sure the 'technical expert advisory committee' includes trained medical clinicians who can adequately assess the value or otherwise of natural health products for the treatment of medical conditions.

### **2. Product approval and ingredient safety process (questions 6-10)**

Although the product approval process appears to be a pragmatic and sound process one key concern remains: The process would require the product sponsor to self-certify that any claims they intend to make about a product would be allowable and also self-certify they had the evidence to support those claims. This is a key area of concern as unrealistic claims about a natural health product can hurt vulnerable people and their families – particularly those suffering from serious disorders (that in some cases may be incurable). We believe that a product sponsor must detail what level of claims evidence they hold during the product approval process and this information be used to assist in making decisions about what claims can be made of a product.

### **3. Claims, labelling and advertising (questions 11-18)**

We believe that it is essential for any claims made about a natural health product to include a reference to the quality and quantity of evidence backing the claim. This information would provide a consumer a means of assessing a claim's

validity. Perhaps the regulator might develop a set of allowed claim statements that would be suitable for different levels of evidence – for instance a claim statement for a ginger based product as anti-motion sickness remedy might claim to be supported by peer-reviewed, published double-blind experiment-based evidence but a claim statement for the same ginger based product as a treatment for influenza might claim to be supported only by a small number of non-double blind studies as evidence.

From our perspective it is essential that the regulator conduct regular audits, particularly around claims made about natural health products – both on labelling and in advertising. This is necessary to protect the vulnerable consumers and their families mentioned above who might be influenced by unrealistic claims.

We also believe that it is essential that any advertising of a natural health product include information about the level of evidence supporting any claims made.

We suggest the development of a ‘code of ethical practice’ for natural health product manufacturers, importers and retailers. This code should set out the ethical standards that these manufacturers and importers must abide by and be enforceable by the regulator.

#### **4. Manufacture (questions 21-22)**

The consultation paper states:

*“It is intended that the Code of Practice for Manufacturing Natural Health Products apply less rigorous requirements than the Code of Good Manufacturing Practice that currently applies to the manufacture of medicines.”*

In general we have concerns with this statement. We believe that all products claiming some therapeutic benefit must be manufactured to the same consistent high standard to ensure the product is safe for the general public. We ask that serious consideration be given to the rationale used to demand ‘less rigorous manufacturing requirements’ for natural health products in the context of the safety of New Zealand consumers.

#### **5. Sanctions and penalties (questions 28-29)**

From our perspective the manufacturers importers and retailers of these products must be made accountable for any false, misleading or deceiving claims they

might make regarding their products. We agree with the sanctions and penalties suggested but urge that deceptive behaviour be treated seriously within the regulations.

## **6. Interfaces**

We agree with the statement on interfaces but urge the importance of differentiating between natural health products and medicines that are regulated under the Medicines Act 1981. We suggest the regulator require a reference to be included on the labelling of all natural health products stating that they are regulated under the [*insert name of new act*] Act. This would provide a definitive differentiation between natural health products and medicines.

Yours sincerely,

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