



Office of Hon Dr Jonathan Coleman

MP for Northcote
Minister of Immigration
Minister of Broadcasting

Associate Minister of Tourism
Associate Minister of Health

15 OCT 2009

Roger Sowry
Saunders Unsworth
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WELLINGTON

Dear Roger

Proposal for the regulation of natural health products

You have asked for some background information for our 21 October 2009 meeting with representatives of the natural health products industry.

Introduction

In April, the National Party and the Green Party announced that we would work together to develop a regulatory system for natural health products that is specific to New Zealand.

Since meeting with industry representatives in May, we have been considering the parameters of the regulatory system. We have taken into account past work, such as that done by the Health Select Committee in its inquiry into the proposal to establish a trans-Tasman agency, regulatory systems in other countries, and World Health Organisation guidance. We have also considered the 'fundamental principles' and the New Zealand Health Trust proposal that were tabled at our May meeting with industry representatives.

Development of a Natural Health Products Bill

We intend to develop a public consultation paper setting out proposals for a Natural Health Products Bill. At this stage, we can offer the following responses in relation to the 'fundamental points' put forward by the industry group.

Separate regulator for natural health products

- We support regulating natural health products separately from food and medicines legislation, and expect that the regulator will be a small unit within the Ministry of Health.

Compliance costs and funding

- The scheme will be fully cost-recovered; however we also consider that there should be parity with the medicines industry. Therefore, we propose that the Crown partially fund post-market costs.
- We propose that the Director-General of Health be accountable for regulatory decisions and that these be informed by a technical advisory group whose members are appointed by the Minister of Health. We want the structure to be as simple and cost-effective as possible, therefore we do not support the idea of a governing body and propose that the regulator be accountable to the public through the Ministry's normal channels (ie, the Statement of Intent, Annual Report, select committee scrutiny etc).

Risk proportionate risk management programme or good manufacturing practice

- We agree that manufacturing standards should be proportionate to risk and propose that the industry group work together with the regulator to develop a principles-based code suitable for the manufacture of New Zealand natural health products.
- We support the suggestion of an online register on which businesses, products and ingredients are notified.

Product claims/evidence/ingredients

- We support the industry group proposals.

Appropriate regulatory advertising code

- We support the industry group proposals and propose also that the scheme contain advertising rules consistent with the principle that products be true to label.

Products exported from New Zealand

- We support the industry group proposals.

Streamlined audits

- We support the principle of a single audit and will expect the regulator to work with the food and medicines regulators to see if this can be achieved given that the different sector audits have a slightly different focus.
- At this stage we are not proposing recognition of third party audits, but are open to considering this as part of the public consultation.

Mutual recognition with key international markets

- At this stage we are not proposing that the regulator take responsibility for developing mutual recognition agreements, but again are open to considering it as part of the public consultation.
- At this stage we are not proposing unilateral recognition, but are open to considering it.

Timeline

We intend to publicly release a consultation paper in early 2010. It will be relatively high level in order to set the parameters of the regulatory scheme.

We intend to draft the bill in the first half of 2010 and the public will have a further opportunity, at a more detailed level, to consider and have input to the bill when it is considered by select committee.

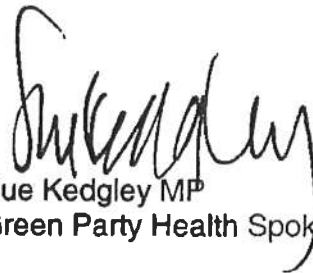
At this stage, we cannot give a commitment as to when the legislation will be enacted, but we will be asking Cabinet to give it a high priority.

We look forward to meeting with you and the industry representatives on 21 October.

Yours sincerely



Hon Dr Jonathan Coleman
Associate Minister of Health



Sue Kedgley MP
Green Party Health Spokesperson

