Technical Alert

New Zealand Natural Health Products Bill - Consultation

Dear member,

The New Zealand Government is developing a new regulatory scheme for low-risk natural health products. Consultation is now open on the proposals outlined in the consultation document and the draft papers below:

- The Regulation of Natural Health Products: Consultation document (docx, 135 KB)
  Page 33 of this document contains a pre populated submission form.
- The Regulation of Natural Health Products: Consultation document (pdf, 135 KB)
- Draft Code of Manufacturing Practice (docx, 199 KB)
- Draft Code of Manufacturing Practice Guidelines (docx, 275 KB)
- Draft Guidelines for Natural Health Products Evidence Requirements (docx, 135 KB)
- Draft list of conditions about which claims can be made (xlsx, 32 KB)
- Draft database of permitted substances

In particular feedback is sought on:

- what the regulations and notices will specify
- labelling requirements
- fees associated with manufacturing and selling permitted NHPs
- type and quality of evidence used to support health benefit claims
- manufacturing requirements
- permitted substances
- conditions about which claims can be made.

The Bill is expected to take effect from June 2016, and the Regulations are expected to come into force shortly afterwards.

Members are invited to provide comments to this consultation for incorporation into the Australian response. Comments can be sent to submissions@cmaustralia.org.au up to the **22 January 2016**. Members are also encouraged to make a submission directly to the MOH on behalf of their own company – final date 5 February 2016.

Note: Submissions on the draft list of conditions about which a claim can be made and the draft permitted substances list will remain open for comment until 31 May 2016.

CMA provided a submission to the NZ Ministry of Health on the Supplementary Order Paper in August 2015. To read a copy of this submission, click here.

Background

The 2012 Government Bill (324-2) introduced draft legislation that consisted of two parts.

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Part 1 of the bill defines a natural health product according to how the product is consumed, its ingredients, and the type of claim of health benefit made. It also proposes the establishment of a regulatory authority within the Ministry of Health, which would recognise decisions made by other authorities, create an advisory committee to advise the authority, and maintain an online database of natural health products.
Finally, part 1 requires the notifier of a natural health product to be a resident of New Zealand.

Part 2 sets out the regulatory scheme. It proposes that before products can be marketed, they would have to be notified on an online database. This process would require the applicant to declare that the product met the scheme's requirements, and the product notifier to hold evidence supporting any claim of health benefit. It provides for the authority to audit, suspend, or cancel notifications; prohibit ingredients; issue export certificates and compliance notices; undertake safety assessments of ingredients; and prescribe fees. Part 2 would establish penalties, a code of manufacturing practice, and mechanisms for appeal and the recall of products. It would also require product notifiers to inform the authority about any serious adverse reactions to products, and any ingredients which were not previously notified.

A copy of the Natural Health Products Bill (2012) is available on the New Zealand Government Legislation website here.

Should you wish to discuss any aspect of this consultation, please contact Emma Burchell on ph. 02 6260 4022 or email: emma.burchell@cmaustralia.org.au

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