



**LEGISLATION ADVISORY COMMITTEE**

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Chair  
Health Select Committee  
Parliament Buildings  
P O Box 18 041  
Wellington 6160

**Medicines Amendment Bill**

1. This submission is made by the Legislation Advisory Committee (LAC).
2. The LAC was established to provide advice to the Government on good legislative practice, legislative proposals, and public law issues. The LAC has produced and updates the Legislation Advisory Committee Guidelines: Guidelines on the Process and Content of Legislation (LAC Guidelines) as appropriate benchmarks for legislation. The LAC Guidelines have been adopted by Cabinet.
3. The terms of reference of the LAC include:
  - (a) to scrutinise and make submissions to the appropriate body on aspects of Bills introduced into Parliament that affect public law or raise public law issues:
  - (b) to help improve the quality of law-making by attempting to ensure that legislation gives clear effect to government policy, ensuring that legislative proposals conform with the LAC Guidelines, and discouraging the promotion of unnecessary legislation.
4. The LAC considered the Bill at its meeting on 30 March 2012.
5. We refer to our letter dated 2 April 2012 about the Natural Health Products Bill. In that submission we made observations that the procedures relating to the appointment of advisory committees could be strengthened to better provide for their

independence. Those procedures appear to be based on those in the Medicines Act, which themselves could be improved.

5. The Bill interacts with the regulation of medicines, food and cosmetics. As the RIS states, "there will be instances where the categorisation of a product could arguably fall under two or more regulatory regimes" (p.2). These 'combination' or 'borderline' products have been recognised as problematic by regulators and scholars. For example, the definition of 'food' may require consideration given that there are products which could be caught by either or both 'food' and 'natural health product'.
6. There are potential issues with the relationship between the Medicines Amendment Bill and the Natural Health Products Bill. Unlike medicines, natural health products do not have a "therapeutic purpose" (see the meanings of 'medicine' and 'medical device' in the Bill and the Medicines Act). It is arguably unclear how the interface between the Medicines Act 1981 (or the Medicines Amendment Bill) and the Natural Health Products Bill will work. For example, it may be currently unclear how the statutory scheduling under the Medicines Act and the Natural Health Products Bill will work. Tryptophan is an amino acid which functions as a precursor for compounds such as serotonin. Tryptophan may be an example of the potential difficulties at the scheduling interface (see our previous submission on Natural Health Products Bill). However, the RIS states that "officials are undertaking detailed work to define the interface between natural health products, medicines, food and cosmetics." (p2).
7. The LAC does not wish to be heard in support of the submission.

Sir Grant Hammond  
Chair  
Legislation Advisory Committee