

## **Summary of Key Issues**

### **1. Notification/pre-approval disproportionate, unnecessary & costly**

- The change to the notification process to include pre-approval processes is unnecessary and disproportionate legislative response. The Bill includes considerable powers to deal with products that are likely to cause harm or make misleading or untrue claims (Clause 16).
- The change to include pre-approval processes imposes a higher legislative standard on NH&SPs than medicines. In general, claims about medicines in advertisements do not require approval (although they are subject to regulation) but certain claims (including claims about particular conditions) are prohibited. The same approach should be adopted for health benefit claims under the NH&SP Bill (which also provides for regulation prescribing requirements and/or restrictions relating to health benefit claims). A list of excluded claims could be identified (which could then only be made if they are approved).
- Pre-approval processes will cost considerably more than a simple notification process.
- The obligation to provide a summary of evidence to support a health benefit claim will result in significant indirect compliance costs. Any summary of evidence provided under this requirement (for a named condition) will need to be reviewed to ensure that any health benefit claim in the evidence is limited to the “allowable claim” ie as approved by the Authority. Any detailed information (such as a scientific paper) is likely to make wider health benefit claims (as defined in the Bill) that the “allowable claim” for any particular product. This is unworkable.
- Claims should be required to be notified with evidence held by the product notifier that supports any health benefit claim. The Authority has the power to call up that evidence and disallow inappropriate claims if necessary resulting in an administratively efficient regulator.

### **2. “health benefit” definition too narrow**

- The definition of “health benefit” (clause 5) must include “restoration” because NH&SPs often restore health in addition to maintaining or promoting health and wellness (egg iron supplements may “restore” low iron stores to healthy levels”).

### **3. The Bill as re-drafted would give the Authority too much discretion/power**

- There is no obligation on the Authority to come up with (or revise periodically), the proposed list of “allowable” conditions (clause 12B).
- Consultation provisions have been narrowed so that the Authority would effectively have the power to select who it would consult with about key matters such as the development of the manufacturing code, fees and regulations (see clauses 27,35 and 47).
- The clause providing for the policy and operational review (clause 48) does not establish the basis on which that review would be carried out, nor does it provide for industry input/consultation.

- The Bill must provide a clear foundation for the operational/policy review and the consultation provisions must revert to those in the original draft (to consult parties “likely to be affected”).

#### **4. Restrictions on advertising disproportionate and unworkable**

- The restrictions on advertisements that relate to named conditions in clause 40C have no exclusion for natural health practitioners, the result being that any product manual (which are in common use throughout the industry) that refers to a condition in relation to a product will effectively require approval by the Authority (as suggesting a product assists in the treatment of that condition). This would be costly and would unnecessarily and unduly restrict consumer information.
- This is disproportionate as compared to Medicines regulation. The prohibition on certain types of advertisements for medicines (section 58 Medicines Act) does not apply to certain health practitioners (section 60 Medicines Act). The other anomaly is that while the Medicines Act provides a defence of “truth” for charges of a breach of the advertising restrictions the NH&SP Bill does not.
- The clause is a disproportionate prohibition and should be deleted. Any misleading claims would be subject to the Fair Trading Act.

#### **5. Onerous re-notification provisions**

- The obligation to withdraw and re-notify a product due to a change in manufacturer does not recognise practical realities.
- The withdrawal of a notification will mean un-sold products still on the market will not be able to be sold legally.
- The clause does not recognise that products may be manufactured either concurrently or at overlapping times by different manufacturers.
- A change of manufacturer should not trigger withdrawal and re-notification of a product. The clause must be amended to allow for notification of more than one manufacturer for a particular product and for amendments to be made to a notification to reflect changes in manufacture.

#### **6. Onerous obligations to report allergic reactions as serious adverse events**

- The inclusion of allergic reactions in the definition of a “serious adverse event” is inconsistent with the World Health Organisation (WHO) definition (and most if not all other countries).
- Medsafe (through CARM) currently collects and reports on adverse events for medicines, vaccines and complementary and alternative medicines (NH&SPs) based on the WHO definition. The addition of “allergic reaction” to the NH&SP definition would result in adverse event reports based on different (and more stringent standards) for NH&SPs than medicines and vaccines.