Senate Standing Committee on Community Affairs
Inquiry into the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013
Submission – NSW Ministry of Health

1. The proposed Amendment Bill is organised via Schedules 1 to 16.

2. Schedule 1 –Advertising. The purpose of the amendments is to clarify that a reference to advertising requirements refers to the requirements of the Therapeutic Goods Advertising Code and strengthens the ability to cancel registration or listing of products from the Australian Register of Therapeutic Goods (ARTG) when serious breaches of the Code occur. These amendments are supported in order to provide enhanced protection of consumers and/or patients.

3. Schedule 2 – Obtaining Information. The proposed amendments appear to clarify and strengthen the powers to obtain information from sponsors of therapeutic goods for the purpose of applications for listing on the ARTG. The amendments also include offences relating to biological and therapeutic devices being brought into line with the provisions for listed and registered therapeutic goods. These amendments are supported to allow for enhanced protection for consumers and/or patients.

4. Schedule 3 – Goods that are not therapeutic goods. This schedule contains amendments to allow the Minister to exclude from the definition of 'therapeutic goods' by way of a legislative instrument, goods which are not intended to be therapeutic goods. These products may include mattresses which make claims to reduce dust mites or bracelets claiming health benefits and increased strength and flexibility, where public health is not likely to be an issue, but are rather a matter for consumer protection law. A further amendment in this schedule allows for the Secretary to remove the entry of goods on the ARTG where the Secretary is satisfied that the goods are not therapeutic goods within the meaning of the Act. These amendments are supported in order for the Therapeutic Goods Administration to focus on its core business to ensure the safety, quality and efficacy of therapeutic goods.

5. Schedule 4 – Restricted representations and prohibited representations. These amendments provide clarification of safeguards on the use of restricted or prohibited representations, including the scenario, where the Secretary allows the use of a restricted or prohibited representation in an advertisement, the Secretary may impose appropriate conditions on that permission. These amendments are supported to allow flexibility in advertising, but at the same time provide for consumer protection from false or misleading advertising.

6. Schedule 5 – Evaluation and registration of therapeutic goods. These amendments reflect that a decision to approve product information for a medicine is an integral part of the decision to register the medicine on the ARTG, and that the content of the product information underpins the registration decision and the basis on which a decision is made after evaluation that a medicine is suitable for registration. These amendments are supported to ensure that the product information is consistent with registration of the product on the ARTG.

7. Schedule 7 – Presentation. These amendments strengthen the protection of the public with powers provided to the Secretary to cancel listing or registration of therapeutic goods due to 'unacceptable' or 'not acceptable' presentations, including misleading or confusing advertising or informational material associated with the therapeutic goods, for example in consumer medicine information. These amendments are supported.

8. Schedule 6 and Schedules 8 to 16. The amendments included in these schedules include proposed minor amendments to procedures, rights of review, definitional changes, offences for false and misleading statements, public notification and generally provide for more certainty, clarity, consistency and transparency in the application of the legislation to provide enhanced protection of consumers and patients.