# Submission on the New Zealand Medicines Amendment Bill

# April 2012


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## We request an opportunity to present to the Select Committee in person.

Medicines New Zealand is the industry association that represents the companies that research, manufacture and supply innovator medicines to New Zealand.

## Our members are:

Abbott Laboratories NZ Limited
Alcon New Zealand Limited
AstraZeneca Limited
Bayer HealthCare Pharmaceuticals
Biogen Idec New Zealand
Boehringer Ingelheim NZ Limited
CSL Biotherapies (NZ) Limited
GlaxoSmithKline NZ Limited
Janssen
Merck Sharp & Dohme (New Zealand) Limited
Mundipharma New Zealand Limited
Novartis New Zealand Limited
Pfizer New Zealand Limited
Roche Products (New Zealand) Limited
Sanofi New Zealand Limited

## Our associate members are:

IMS Health (N.Z.) Limited
Quintiles Pty Limited
Healthcare Logistics

## Context

We believe the Medicines Amendment Bill needs to be closely aligned with the expected outcomes of ANZTPA to prevent confusion during the transition from two separate regulators to a single Trans-Tasman regulator.

## Substantive issues

We welcome the Government's review of the Medicines Act as there are a number of aspects of the existing Act that are outdated and do not support the efficient regulation of medicines in New Zealand.

We consider that the scope of the Amendment Bill is too narrow and that it should be broadened to include aspects not already covered (as described in points number 7, 8 and 9 below).

## Section 5

1. We support the intention to improve the definitions of what constitutes a medicine and a medical device. We further consider that aligning the definition of medical device with that in Section 41BD and a medicine with that in Section 3 of the Australian Commonwealth Therapeutic Goods Act 1989 would be appropriate. Currently the Bill only partly aligns these definitions.

## Section 8

2. This section modifies the Medicines Review Committee process, but does not clearly define the powers of the Medicines Review Committee regarding the possibility to overturn a decision or make other recommendations. The powers of such a committee should be clearly defined. As the Bill introduces substantial new powers for the regulator, (such as the ability to impose conditions on approvals) it is necessary to ensure that these new powers are subject to an effective review process.

## Section 12

3. Relating to Section 20A(1)of the Medicines Act - The proposed wording in the Bill is such that the Minister "must not give consent" unless he or she is satisfied that the benefits outweigh the risks if the medicine. Such wording would make the Minister liable to legal challenge in the face of individuals or groups considering that some of the risks associated with medicines outweigh the benefits. We propose that the wording be more neutral and aligned with the Australian Commonwealth Therapeutic Goods Act wording such as:

The Minister may give consent or provisional consent to the distribution of a medicine where he or she is satisfied that *the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established*.

4. Relating to section 20A(2) of the Medicines Act - This clause introduces the ability of the Minister to impose conditions on the approval of a medicine. We consider that it may at times be appropriate to impose such conditions, but it is essential that the basis on which conditions are to be imposed is defined in the Bill. We believe a mechanism for defining these conditions should be described in the Bill or at least should be required in regulations and referred to in the Bill. Portions of Section 28 of the Australian Commonwealth Therapeutic Goods Act could be used for better defining the intention of the new powers introduced by the Bill in this area. The final wording should also be used in Section 22(3) of the Medicines Act.
5. Section 22(4) We recommend that the Bill introduces timeframes within which the notification and Gazettal of the Ministers decision should occur.
6. Relating to Section 23 of the Medicines Act - Procedure for application for Minister's provisional consent. The basis for requiring provisional consent is not defined. The need for provisional consent is out of alignment with other major international regulators and there appears to be no need for this in medicine regulation in New Zealand. Furthermore, the Bill generates the ability for conditions to be placed on full consent, one of the previous uses for the Section 23 consent process. We recommend that the Medicines Bill be amended to remove Section 23 of the Medicines Act relating to provisional consent.

   Failing removal of section 23 in its entirety, the Bill should define the need for and basis on which provisional consent is considered necessary. Furthermore, if Section 23 is not removed, the Bill should define a process and basis for converting from provisional consent to full consent.

## Additional aspects for inclusion in the Bill

7. Currently industry self regulation is important to ensure that interactions between medicine suppliers and health professionals is conducted in an ethical manner. This self regulation however can only be effectively applied to member companies of the suppliers associations such as Medicines New Zealand and the New Zealand Self-Medication Industry Association that administer their respective Codes of Practice. We recommend that the Bill introduce the requirement for all suppliers of medicines in New Zealand to comply with the industry Codes of Practice when marketing their products.

8. The interface between the Medicines Act and the Misuse of Drugs Act (MODA) and corresponding Regulations, should be clarified and simplified to contain all labelling requirements in the Medicines Amendment Bill. The current MODA contains requirements around labelling that are not harmonised with Australia and to enable these being harmonised under ANZTPA, the appropriate labelling requirements should be contained in the Medicines Amendment Bill. This refers particularly to the labelling requirements for medicines and the requirements for Controlled Drug Registers, which emanate from the Misuse of Drugs Regulations.

9. Currently there is no provision in New Zealand law to promote medicines approved internationally, but not in New Zealand to international conference delegates. International practice is that many countries (including Australia and the United States of America) allow for conferences to contain enclosed areas where companies can promote medicines that have regulatory approval in the countries from which the conference delegates come. Promotion of such medicines to international delegates would be strictly enforceable to ensure that local delegates are not receiving any promotional material or information on unapproved medicines in keeping with the existing Medicines Act.

   We recommend that the Medicines Amendment Bill include a clause to allow international medicine sponsor companies to promote products that are approved in other regulatory jurisdictions, but not in New Zealand, to conference delegates who reside and work in those jurisdictions. The clause should also prohibit such promotion to New Zealand practitioners.

## Conclusion

We support the updating of the Medicines Act to align some aspects with international practice, but consider that there are further changes that should be included. The changes proposed should be in alignment with, or lay the foundation for the ANZTPA process.

We recommend that the transition period to the new regulatory processes resulting from the Medicines Amendment Bill be clearly defined in consultation with industry.

**Kevin Sheehy**

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**Medicines New Zealand**
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