



Australian Self-Medication Industry Inc
Suite 2202, Level 22, 141 Walker Street,
North Sydney NSW 2060
PO Box 764, North Sydney NSW 2059
Ph +61 2 9922 5111 Fax +61 2 9959 3693
Email: info@asmi.com.au www.asmi.com.au
ABN 55 082 798 952

2 December 2008

Mr Patrick Laplagne
Assistant Commissioner
Productivity Commission
Locked Bag 2 Collins Street East
MELBOURNE VIC 8003

Dear Mr Laplagne

Please refer to the Productivity Commission's draft report on Mutual Recognition. ASMI wishes to offer the following comments about the draft.

About ASMI

ASMI represents the interests of manufacturers and sponsors of non-prescription medicines in Australia. We maintain close ties with our opposite numbers in New Zealand the NZSMI, but the views expressed here are ours alone.

ANZTPA

The Commission has recounted in the draft report the unfortunate events leading to the former NZ Government's inability to secure the legislation which was to give effect to ANZTPA in New Zealand. Consequently, the vast body of work undertaken by industry and governments alike was put on hold. Although ASMI made a large number of submissions in response to consultation papers, we never did learn which of our proposals had found favour with the officials. That is, the consultation as a one-way process.

ASMI has been a strong and consistent supporter of the ANZTPA idea, even going to New Zealand to argue the case there. It is perhaps not surprising that industry did not favour some of the proposed new arrangements. On the whole, however, the proposed regime represented a significant step forward towards best regulatory practice.

ASMI therefore believes that the Australian and New Zealand Governments (both as it happens, new to office) should try to revive ANZTPA. However, the Governments should set a realistic but short timetable within which to achieve the revival.

If it becomes apparent that the NZ Government or Parliament is unwilling or unable to secure the necessary legislation, we consider that Australia should abandon further effort.

Products to be regulated by a revived ANZTPA

There have been some suggestions that ANZTPA might be revived if some classes of products were excluded from its regulatory scope. Products called dietary supplements in New Zealand have been mentioned.

ASMI is firmly of the view that the ANZTPA regulatory scheme must cover all products which make a therapeutic claim, as that term is currently defined in Australian legislation. We will not support any scheme to “exempt” or “exclude” dietary supplements, or any other class or group of therapeutic products.

Regulatory improvements – Australia

ASMI believes that Australia should not delay further adopting the best of the ANZTPA proposed reforms on an Australia-only basis. Further, we do not believe the Australian Government should delay these reforms until the NZ position is clear. We should press ahead now.

In particular, reforms are long overdue in relation to

- scheduling of medicines;
- advertising of therapeutic products.

ASMI has recently sought clarification as to the Government’s intentions in both these areas. As yet, we have not had replies to our letters.

ASMI believes that there are many aspects of therapeutic products regulation that do not measure up to COAG regulatory principles. Improvements should not be delayed indefinitely against the possibility that New Zealand will come on board with ANZTPA.

Mutual Recognition

ASMI supports the intention and thrust of draft recommendation 7.2, subject to the observations made above. Therefore, we submit for the Commission’s consideration some amended wording which we feel would reflect more completely industry’s concerns:

- “(1) (a) The Australian and New Zealand Governments should resume negotiations to establish a joint regulatory scheme for therapeutic products, with a joint agency to administer the scheme, as a matter of urgent priority.
- (b) The two Governments should agree on a time limit within which agreement must be reached; within that period, the special exemption for therapeutic goods should continue.
- (c) Beyond that period, however, a permanent exemption should be put into effect.
- (2) In the meantime, Australia should press ahead with necessary reforms to its therapeutic goods regulatory regime, with a view to adopting best practice reforms originally proposed under ANZTPA, particularly regarding the scheduling of medicines and advertising of therapeutic goods”.

Further consultation

ASMI would be happy to assist the Commission further in this inquiry, if you so desire.

Yours sincerely

A handwritten signature in black ink, reading "Juliet Seifert". The signature is written in a cursive, flowing style with a large initial 'J' and a long, sweeping underline.

Juliet Seifert
Executive Director