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The Secretary
Joint Standing Committee on Treaties
Parliament House
CANBERRA ACT 2600

Dear Secretary

I have been asked to submit to the Committee the attached submission relating to the Treaty with New Zealand on a joint therapeutic products agency. The submission is lodged on behalf of the Australian Self-Medication Industry.

My clients will be pleased to appear before the Committee if it so wishes. Also, please let me know when the Committee authorises publication of the submission.

Yours sincerely

George Brownbill
Government Relations Consultant
Email g.brownbill@aciltasman.com.au

End.

Submission to the Treaties Committee of the Parliament of Australia

In relation to

the Agreement between Australia and New Zealand to establish a Joint Scheme for the Regulation of Therapeutic Products

by

Australian Self-Medication Industry

30 YEARS

AUSTRALIANS MEDICATING INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

April 2004

Contents

Executive Summary

- The Australian Self-Medication Industry (ASMI), representing manufacturers of non-prescription (OTC and complementary) medicines in Australia, strongly supports the proposed Joint Australia-New Zealand Therapeutic Products Agency,
- We propose that the Treaties Committee recommend ratification of the Treaty.
- We support the Treaty because:
  - it will advance CER;
  - Australia and New Zealand are pretty much one market for therapeutic products already;
  - further market efficiencies can be achieved;
  - there should be cost savings to industry; and
  - there is an opportunity for further regulatory leadership in the Asia/Pacific region.
- ASMI has considered other forms of harmonisation but prefers the joint agency approach.
- The Agency must regulate all therapeutic products, with a risk- and science-based approach, specifically extending to those complementary medicines known in New Zealand as "dietary supplements".
- The regulatory scheme should extend to sole traders and intra-State traders and there should be no capacity remaining for State and Territory Governments to evade or prevent a uniform system for scheduling drugs.
- The proposed cost-recovery arrangements are unfair to industry, being based on "full cost recovery" rather than (as the Productivity Commission recommended) "fee for service".
- ASMI has not seen drafts of the enabling legislation, nor of the proposed Rules and Orders. We may wish to make further comment, once these are available.

1. Introduction

1.1 Australian Self-Medication Industry

The Australian Self-Medication Industry (ASMI) represents manufacturers of non-prescription medicines in Australia. A brief overview of ASMI's charter, and a list of our members, appears at Attachment 1.

The Committee will note, from ASMFs membership and from material later in this submission, that ASMI represents makers of non-prescription medicines, whether regarded as "OTC" or as "complementary healthcare products". That is, our members accept and understand that a unified regulatory system for all therapeutic goods is in the public interest.

ASMI has been, and remains, **a strong supporter of the proposed joint agency.** It follows that we **support the Treaty and urge the Committee to recommend that it proceed to ratification and entry into force.**

That said, however, there are some issues which remain unresolved. These arise from the fact that neither the draft legislation nor the proposed Rules and Orders have yet been published. We are therefore in no position to comment beyond the very broad level of principle which the Treaty addresses.

1.2 Structure of this submission

In Section 2, we respond to the question — do Australia and New Zealand need a joint agency to regulate therapeutic products?

In Section 3, we stress that **all** therapeutic products should be covered by the Scheme, including those products which have been regarded in New Zealand as "dietary supplements", and that in the Australian Constitutional sense, the Scheme must "cover the field".

Section 4 relates to issues of cost recovery.

1.3 ASMI supports the joint agency approach

Ever since this proposal grew out of the Trans-Tasman Harmonisation and Mutual Recognition initiatives, ASMI has made strong and positive contributions to the debate on a proposed joint agency. As well, we have been pleased to have had a variety of opportunities to take part in consultations organised by the Working Party, both in Australia and New Zealand. These have been well-managed and helpful to industry.

1.4 ASMI's and NZSMI's joint position

ASMI and its New Zealand counterpart, the New Zealand Self-Medication Industry (NZSMI), have drawn up a joint statement of principal issues to which we jointly subscribe in relation to the Treaty and the new agency. This statement is reproduced at Attachment 2.

2. Do Australia and New Zealand need a joint agency to regulate therapeutic products?

2.1 A joint agency will advance the national interests of Australia and New Zealand

The Australian and New Zealand industry are in no doubt that **a joint agency is the right way forward for our two countries,** for these reasons:

- the agency represents **an important step forward in** CER. Unlike the FSANZ, the joint agency will actually licence products for sale in either country. This truly advances our common economic future;
- the therapeutic products markets of New **Zealand and Australia are essentially one market** now. Regulatory differences between the jurisdictions are mostly minor and as such are little more than an impediment to efficient operation in the one market;
- by the same token, the joint agency proposal affords Australia an opportunity to iron out minor but annoying idiosyncratic differences between the States and the Commonwealth, presenting industry with **further market efficiencies;**
- the joint agency is expected to bring about **cost savings** because it will eliminate a lot of "double-doing" in both Wellington and Canberra, when, in the past, the same product has been up for approval under both regimes;[1]
- founded on international best practice, and building on TGA's and Medsafe's already high reputations in our region, **the joint agency will assume a position of leadership in the Asia-Pacific area.**[2]

2.2 The New Zealand and Australian markets for therapeutic products

The Australia-New Zealand market share of the world medicines market is about 2%. Together, our population is about 23 million and the demographics make it fairly homogenous. It makes sense for us to combine our regulatory resources in respect of a market which is already integrated.

1 Note, however, that the degree of cost saving depends on how the intended cost recovery regime will operate — see Section 4.

2 Art. 19 of the Treaty provides for third parties to accede to it. This represents a. significant opportunity for regional harmonisation.

Trans-Tasman trade in "pharmaceuticals" is significant, in both directions:

	12 Months Ended 30 June 2001	12 Months Ended 30 June 2002	June Quarter 2002
Australian Exports to New Zealand ($Am)	266	279	64
Australian Imports from New Zealand ($Am)	38	42	8

Source: ABS, International Merchandise Trade 5422.0, June Quarter 2002 (p48). These are the latest available figures.

The present structure of the Australian and New Zealand industries operates on the basis of an integrated, and mutually complementary, market.

While there are locally based medicines' producers in both New Zealand and Australia, a very large part of the market is served by local agencies or subsidiaries of global firms. To them, Australia and New Zealand are, economically and in their organisation arrangements, in the same area or region.

2.3 Is a joint agency preferable to other forms of regulatory harmonisation?

Although there have been points of difference between the Australian and New Zealand regulatory systems for therapeutic products, ASMI considers that the systems are more similar than different. We therefore accept the conclusion in the Regulatory Impact Statement that:

> "The arrangements for legislation outlined in the Treaty provide the best chance of establishing truly harmonised regulatory arrangements. Industry need comply with only one set of requirements in both Australia and New Zealand."[3]

[3] *Regulatory Impact Statement,* p. 34.

3. The joint agency should regulate all therapeutic products

3.1 AH therapeutic products should be regulated to some degree

ASMI retains an open mind on precisely **how,** and to what extent, various classes of therapeutic product should be regulated. **But** we **are in no doubt that all those products that, under Australian law, are "therapeutic goods", should be regulated by the joint agency as such in both countries.** Moreover, we are in no doubt that those who offer for sale products making a therapeutic claim should be required, under the advertising controls, to substantiate those claims.

There are two main reasons why ASMI takes this basic position:

- *First,* for **protection of the consumer.** The medicines industry exists to serve the needs of the consumer. People's expectations are that, by taking or using a medicine, it will have, or bring, the benefits for them claimed for it. Consumers are likewise entitled to know that the products offered for sale meet safety and quality standards, as stipulated by an appropriate science-based regulatory agency.
- *Secondly,* to ensure the maintenance of **business competition on a level playing field.** If all products are regulated in accordance with the same principles, all are equal in the marketplace. Since the "marketplace" is really Australia and New Zealand, the level playing field must extend across the economies of both jurisdictions.

3.2 A risk- and science-based system

The underlying principle of the Therapeutic Goods Act (Aust.) is that all products must satisfy the tests of quality, safety and efficacy.[4]

This provision applies to products to be offered for sale, whether as prescription only, or non-prescription (OTC and complementary healthcare products). The former are required to be "registered", as do most OTC products, but some of the latter can be "listed".[5] The difference is that, while all goods must be assessed for quality and safety, only those seeking registration must also be assessed for efficacy. Nevertheless, the "listables" must hold efficacy data sufficient to substantiate any therapeutic claim a sponsor makes, whether on the label or in advertising.[6]

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4 The Therapeutic Goods Act (Aust.), sub-s. 4 (1) reads:
"(1) The objects of this Act are to do the following, so far as the Constitution permits:

(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

(i) used in Australia, whether produced in Australia or elsewhere; or

(ii) exported from Australia."

5 All goods, whether listed or registered, are entered on the Australian Register of Therapeutic Goods (ARTG), which, in part, is open to public inspection.

6 ASMI administers under delegation from the TGA an advertisement pre-clearance system and a complaints process. ASMI's delegation relates to broadcast advertisements for all products and to all OTCs other than mainline media. These arrangements are in the process of being harmonised with NZ in preparation for the entry into force of the Treaty.

In both Australia and New Zealand, the substances which make up the ingredients for therapeutic goods are subject to a system of "scheduling". The Australian *Standard for Uniform Scheduling of Drugs and Poisons (SUSDP)* draws up Schedules detailing the degree of access the public should have to particular medicines.[7] These decisions are based on risk assessment principles.[8] New Zealand is represented on the Australian Committee (the National Drugs and Poisons Schedule Committee), which draws up the *SUSDP*. The higher the Schedule, the more restricted the access.

So, in general, the regulatory classification of medicines looks like this:

Product	Whether registered or listed	Schedule
Prescription medicines	R	S4 — Prescription Only
Non-prescription products (including OTCs and complementary health care products)	R	S3 — Pharmacist Only
higher risk		S2 — Pharmacy Only
↕		
lower risk	L	Unscheduled

These principles of risk management apply to all therapeutic goods. The system applies equally to so-called "pharmaceutical" products as it does to "complementary" medicines. Indeed, it is not a distinction the scheduling system draws.

The system of classification is very similar in New Zealand, except that some "complementary medicines", are excluded, being dealt with instead as foods under the Dietary Supplements Regulations (NZ.). However, substances used in dietary supplements with recognised medicinal use are still controlled by the New Zealand Medicines Classification Committee, which governs the scheduling process. This scheduling process is largely harmonised with the Australian *SUSDP*.[9]

3.3 Defining a therapeutic product

What is a "therapeutic good" under Australian law? The definition is found in s.3 of the Therapeutic Goods Act (Aust.), the key parts of which are in the box.

7 And other "poisons", such as agricultural, household and veterinary chemicals.

8 Therapeutic Goods Act (Aust), s 54E.

9 A notable example is that NZ has tighter restrictions on the herbal ingredient Senna *(Cassia angustifolia)*, the presence of sennosides making it Pharmacy Only, whereas in Australia the herb and its constituents are unscheduled.

Box 1: Therapeutic Goods Act (Aust.)
definition of "therapeutic good" and "therapeutic use"

Therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) Included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(e) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Food Standards Australia New Zealand Act 1991; or

(f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

Therapeutic use means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or

(b) influencing, inhibiting or modifying a physiological process in persons or animals; or

(c) testing the susceptibility of persons or animals to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy In persons; or

(f) the replacement or modification of parts of the anatomy In persons or animals.

In New Zealand, on the other hand, some products which would be caught by the Australian definition of therapeutic goods are not regarded, and thus not regulated, as medicines, unless they make or imply a therapeutic claim.

3,4 The Treaty should apply to all therapeutic products

ASMI considers that the Treaty is correct in providing that all therapeutic products will be covered by the Scheme.[10] Article 2 of the Treaty establishes a Scheme "for the regulation ... of therapeutic products". This has to be read, however, with Article 10, which allows certain substances to be declared as being or not being therapeutic products. These declarations are contemplated to be made by means of Rules or Orders. While ASMI is familiar with the way in which borderline cases are now dealt with under s. 7 of the Therapeutic Goods Act (Aust.), we have not seen draft Rules or Orders and thus cannot comment on whether the same principles are intended under the joint agency.

In ASMI's view, it is very important that substances (including those now classified in NZ as "dietary supplements") that do make therapeutic claims be regulated as

10 Treaty, Art. 1, definition of "therapeutic product" and "therapeutic use" — these definitions closely follow the Therapeutic Goods Act (Aust) — see Box 1. See also Treaty, Art. 10.

medicines and not as foods. **Our support for the Treaty is conditional upon our being satisfied that the proposed Rules and Orders will achieve that outcome.**

We are aware that some, especially in New Zealand, take a contrary view. There have even been calls for separate institutional arrangements to regulate the complementary medicines sector. For the reasons set out above, ASMI does not support this view. We consider that it would be inimical to the design and purpose of the Treaty if whole classes of therapeutic products could "opt-out" of the regulatory scheme by means of Rules or Orders. **We trust that there is no intention that Article 10 will be used to achieve such an outcome.**

This is now also important due to the announcement by the Australia New Zealand Food Regulation Ministerial Council, on 12 December 2004, that, in future, foods making health related claims in terms of context to diet will be subject to formal regulation.[11] As such, the opt-out of Dietary Supplements in 'pharmaceutical presentation' in New Zealand would place that industry at a market disadvantage with regard to the New Zealand food manufacturing industry as well as the Australian food and medicines manufacturing industries.

3.5 The joint regulatory scheme should apply to all who deal in therapeutic products

In para 28 of the *National Interest Analysis,* it is said that an issued raised with the States and Territories was:

> "the capacity for the Agency instead of State and Territory authorities to regulate sole traders (individuals who trade in therapeutic products only within a State or Territory)."

It was stated that "no significant concern" was raised by the States and Territories in relation to this matter. However, in para 29, it is said:

> "The main concern raised by States and Territories was the future of their role in the regulation of access to, or the availability of, scheduled drugs and poisons. They were assured that the Agreement would not be used to vary their existing roles and responsibilities in these areas. Consultation will continue with States and Territories through the exposure draft of the legislation."

ASMI regards the statement at para 28 as correctly describing the Constitutional position. By virtue of the Treaty, the Parliament of the Commonwealth will be able, under the external affairs power, to extend the operations of the successor to the Therapeutic Goods Act to sole traders. In the light of this, we view with some concern the passage in para 29, which appears to suggest that the individual States may wish to retain a discretion to influence the uniform scheduling arrangements.

Industry has been waiting for years now for the outcome of the "Galbally review" of the scheduling arrangements. That review was critical of the States' propensities to intervene in individual scheduling decisions.[12]

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11 http://www.foodsecretariat.health.gov.au/communiques/03_12dec.htm.

12 For example, access conditions for certain analgesics for no reason other than State political preferences. Such idiosyncratic differences are very costly and irritating to industry.

ASMI has strongly supported the joint agency at least in part because we expected its regulatory activities within Australia to "cover the field". We note with some concern that "consultation will continue with States and Territories through the exposure draft of the legislation". Any **provision in that legislation that would extend to the States an entrenched discretion to** vary **scheduling decisions in often minor or subtle** ways **will be of serious concern to ASMI.**

4. Cost recovery

Article 15 of the Treaty relates to funding for the joint agency. Para 15(2)(a) says that the Agency's fees and charges shall:

> "be designed to recover the full costs of the Agency's operations of the Scheme in an efficient and equitable manner".

Para 15 (3)(b) requires the Ministerial Council to "ensure stakeholder representations are consulted *where appropriate"* (our emphasis).

Based on our experience with fee-setting by the TGA, ASMI has some concerns about these provisions.

First, we take issue with the so-called 100% cost-recovery principle. The Productivity Commission enquired extensively into Commonwealth agencies' cost-recovery policies and preferred "fee for service" rather than "whole of agency" schemes. In our view, the TGA performs a variety of functions which are of a "policy" or "public health" nature and from which industry receives no direct benefit. Industry should not fund these activities which benefit all taxpayers.

In our view, there is no warrant for the principle set out in Article 15 (2)(a) for "full cost" recovery. The Rules should clearly establish a "fee for service" and not a "whole of agency" approach.

Our *second* concern relates to the proposed process for consultation with "stakeholders" — a term which is not defined but which could include others than industry which is nevertheless expected to pay 100% of the new agency's costs.

Moreover, the consultation is no more than that. The Ministerial Council is under no obligation to heed any views that may be offered.

Finally, the consultation only takes place "where appropriate". How and by what means is it decided that consultation is or is not appropriate?

The cost-recovery arrangements set out in the Treaty were the subject of no discussion with industry, which will apparently be asked to pay the full costs of whatever the joint agency decides are its costs. Since the agency is subject to direction by the Ministerial Council, industry has been put in the position of simply accepting any level of costs Ministers determine, whether reasonable or not.

Industry's support for the Treaty is thus conditional on further discussion with us on fees and charges, and a satisfactory resolution of the 100% recovery policy. We note that the TGA is commissioning a review of its present fees and charges regime and industry's views will be presented to that review.