Australian
Consumer & Specialty
Products Association
ABN 83 205 141 267

ACSPA

The Director
Trans -Tasman Group
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

SYDNEY OFFICE
Street Address:
Dalgety Square
Suite C7, 376 - 428 Wattle Street
Ultimo NSW 2007
Postal Address:
Dalgety Square
Suite C7, 99 Jones Street Ultimo NSW 2007

Tel: 61 2 9281 2322
Fax: 61 2 9281 0366
Email: bcapanna@acspa.asn.au
gmacalpine@acspa.asn.au

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Dear Sirs

Re: A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products - Discussions Paper (June 2002)

Thank you for the opportunity to comment on the above paper and thank you also for allowing an extension to the deadline.

ACSPA is the national industry association which represents the manufacturers and marketers of formulated consumer and specialty products and their raw material suppliers. Our members' products include all types of cleaning agents, personal care products, disinfectants, hygiene products, adhesives and sealants, protectants and other treatment products used in the household, and by industries and institutions. Member companies range from large to very small enterprises and are located all around Australia (a copy of our current membership list is attached). The current estimated turnover of the Australian industry is approximately $A3 billion (ex-factory).

Our members products are not core to the current Therapeutic Goods Act and are 'caught up' in the legislation at the interfaces between medicines and cosmetic products (eg suncreens, antibacterial handwashes, antidandruff shampoos), and devices and disinfectants. The majority of these products are not currently regulated in New Zealand as therapeutic goods and as such, will be greatly affected by the changes proposed.

Accordingly, our responses to the issues raised in the Discussion Paper focus on

- definitional issues between Australia and New Zealand;
- governance issues and in particular the need to ensure meaningful industry consultation, input and representation;
- regulatory requirements for medicine classes I and II, and devices;
- the implementation/transitional arrangements; and
- other selected issues.

Our submission also has the support of the Cosmetic, Toiletry, and Fragrance Association (CTFA) as it relates to their sector's products.

For clarity, the underlined sections of the following reflect those areas that need further expansion by the Trans -Tasman Group to enable more meaningful comment.

Definitional Issues

Industry has been assured that the regulatory framework for the Joint Agency will be developed and subsequently operate in accordance with the COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies.

It would be a departure from these guidelines to automatically accept the definition of a therapeutic good as interpreted by Australia and/or New Zealand and impose additional pre-market barriers on products not previously regulated in the other country.

The new scheme should not perpetuate unique Australian or New Zealand requirements but look to best practice and international harmonisation - best practice being based not on the adoption of the most onerous/stringent regulatory requirements but on an appropriate risk resource allocation to achieve a cost effective risk management system that strives to protect public health and safety in partnership with its stakeholders.

It should therefore be possible to reconsider a number of product categories and make these, with appropriate levels of self-assessment and/or certification, exempt or even excluded from the legislation.

In particular, our industry is very concerned about the current level of regulatory control imposed on products that are at the interface of cosmetics and other cleaning/disinfectant products, particularly the requirement for a manufacturing licence where this is not required internationally.

In the forthcoming months, the industry will provide submissions to the TGA to address these issues in the following product categories:

- **Antidandruff shampoos -** we have already raised our concerns with the TGA regarding a recent proposal to increase the level of regulatory control for well known substances used in these products. A formal submission on an alternative to the TGA's proposal is currently being formulated and will be provided under separate cover.

- **Sunscreens and moisturisers that contain sunscreens -** ACSPA supported the initial submission made by the CTFA to the relevant branch of the TGA and we will further expand and clarify these proposals. We do not therefore support the proposed criteria for categorising sunscreens as detailed in Part E 2.4 Suncreens (pages 80 -81) and would refer the Trans -Tasman Group in the interim to the CTFA's submissions.

- **Antibacterial handwashes -** we have already raised our concerns about the inappropriate level of controls currently imposed on these products ie as registrable medicines requiring GMP licensing and we will expand our alternative proposals under separate cover.

- **Toothpastes -** these products, under specific circumstances are not regulated in Australia as therapeutic products but are regarded as 'related products' in New Zealand. We believe that the Australian approach is more appropriate and if necessary for clarity, industry will develop guidelines on the claims and 'specific circumstances' at this particular interface.

- **Cosmetic claims guidelines -** the industry, in concert with the above proposals will redraft guidelines to provide greater clarity at the broader interface between medicine and cosmetic regulation. This process too has already been raised with the relevant branch of the TGA.

- **Exempt products -** we are also reviewing other currently "exempt" products in Australia and will make additional recommendations as necessary. In this regard, on page 147 it is suggested that some medicines currently exempted from listing and registration in Australia would become liable for product licensing under a joint agency - we would seek your clarification and/or examples of such products.

Therefore while we agree in principle with the overall scope, risk based approach and product licence concept of the proposed regulatory framework, these definitional issues must be resolved in the short term.

We believe that the consideration of these product categories should move forward in parallel with the joint agency discussions but not be predicated on it proceeding, nor linked to the proposed timetable for implementation of the Joint Agency. We would however wish to engage Medsafe in the dialogue to facilitate the implementation of the agreed outcomes as part of the Joint Agency.

With regard **therapeutic devices** and the related disinfectants controls, we are currently endeavouring to clarify with the Devices Branch the impact on our sector of the introduction of the new legislation based on the principles endorsed by the Global Harmonisation Task Force (GHTF). A meeting has been put in place for 29 August 2002 and further comment will then be provided if necessary regarding any outstanding definitional and/or additional transitional issues (refers specifically to Part G - Regulation of Medical Devices).

With regard **other therapeutic products** ie hospital grade and household disinfectants, the Discussion Paper (Part G - Regulation of Medical Devices Section 3.1 Other Therapeutic Products page 130 - 131) proposes that these products would be regulated by the Joint Agency under a contract, but in New Zealand, they would continue to be regulated by the Environmental Risk Management Authority (ERMA) under the Hazardous Substances and New Organism (HSNO) legislation.

A number of important questions arise:

- why would these products, if ultimately defined as therapeutic goods, not be part of the Joint Agency and its legislation?
- ″under a contact" with which other organisation?
- is the Trans -Tasman Group proposing a permanent exemption from the Mutual Recognition Arrangements for these products?

The proposal to exclude these products has put forward without any prior discussion with industry and without any rationale in the Discussion Paper to support the suggestion. It cannot therefore be supported. We would respectfully request an explanation as to the basis of the proposal as soon as possible.

We would also take this opportunity to suggest that the resultant New Zealand legislation to support the Joint Agency should mutually exclude products from the HSNO legislation - while self apparent to avoid unnecessary duplication, this is not currently the case with some products defined as ‘related products’ in New Zealand eg antiseptics.

And with regard the opt-out provisions suggested in the Discussion Paper as they relate to product categories and definitions, these certainly must be evidence-based however is it envisaged that these would be subject to regular review?

Governance Issues

ACSPA actively participated in the governance and accountability consultation meeting held in Sydney on Friday 19 July 2002. While the outcomes of that meeting are not yet available, we do not intend to reiterate our comments made at that meeting, other than in broad terms:

- If it is still the intention of the Trans -Tasman Group to recommend separation of policy development and implementation of regulatory requirements, industry must be confident that processes exist to provide for meaningful consultation and input from all the relevant and affected sectors at BOTH levels ie policy and regulatory requirements, as well as appropriate ongoing oversight on implementation and application. This is particularly important considering the extent of decision making powers proposed to be ascribed to the Ministerial Council and the Managing Director.

- As per precedent in other areas, it would appear possible to recommend the formation of a representative Ministerial Council Advisory Group to facilitate this important industry consultation process.

- The interpretation of what constitutes policy and what constitutes regulatory requirements needs to be better explained.

- The Board is proposed to be responsible for the Agency's "strategic direction" (and financial performance). This too needs further explanation and clarification of the scope in relation to policy and regulatory requirements.

- Concerns have been raised regarding additional impacting legislation eg Official Information Act in New Zealand and the potential inequities that this could raise if not properly investigated. It is respectively requested that the Trans -Tasman Group expand on this area further and provide its analysis and recommendations for public comment

- We would seek reassurance that the Rules and Orders and Guidelines will all be subject to extensive consultation with industry to ensure the original intent of the Act (once agreed) is retained and the ramifications of any changes can be fully discussed and understood.

- With regard the key influences to the internal organisation, it has been suggested that these include:

    - product types/categories to be regulated and the level of that regulation
    - international harmonisation
    - operational efficiencies and expertise

It is extremely difficult to provide any additional meaningful comment on the adequacy of the mechanisms for governance and consultation in the absence of these requested expansions.

Should the outcomes of the aforementioned consultation meeting not reflect all of the comments ACSPA deem important, we will provide additional comment on this topic.

Regulatory Requirements

Our comments on the applicability of the regulatory requirements to our sectors products can only be effectively made upon final resolution of the aforementioned definitions and product categories. (For example, Table 6 on pages 42 - 46 will require modification as a consequence of our recommendations.)

This is particularly relevant to proposals such as extending the requirements for Consumer Medicines Information, tamper evident packaging, excipient evaluation, drug master files, proprietary ingredients, and export only products to all therapeutic goods generally. The proposals as set out in the Discussion Paper are not acceptable to our industry using the current definitions and interpretations.

We would also make the following broad comments:

- There should be flexibility to **transfer applications and assessments** between relevant branches of the proposed Joint Agency and with additional criteria to include product presentation eg packaging and labelling initiatives.

- The **Expert Committees** proposed should have membership relevant to products being considered eg devices include sterilants and disinfectants. There also needs to be a mechanism to ensure an element of consistency between the Committees and their approach to eg types of claims, information requirements.

- With regard **scheduling,** it is difficult to provide extensive comment as the final Galbally Report and recommendations have not yet made available to industry. That said, it may not be appropriate therefore to link the implementation of recommendations to the timeframe of implementation of the Joint Agency. We would also point out that some "devices" and "other therapeutic products" may contain substances included in Schedules 5 & 6 and no provision and/or processes appear to have been considered for these circumstances.

- **Confidentiality** of formulations is extremely important to our sector, and the industry must feel confident that commercial-in-confidence material will be respected within the proposals for the Joint Agency. The review of the ramifications of impacting legislation previously mentioned is also relevant to this point.

Implementation/Transitional Arrangements

Again, the acceptability of the implementation / transitional arrangements to our sector will be substantially reliant on the satisfactory resolution of the definitional issues identified.

We would add however that in accordance with the COAG principles, to facilitate transparency and compliance, to minimise the potential for bureaucratic discretion and to ensure efficiency in the resources required for implementation, the Rules, Orders and Guidelines must be finalised and available well in advance of the commencement of the new scheme, followed by a minimum of a 5 year transitional period for all products. We therefore do not agree with the proposals set out in the Discussion Paper.

The availability of such documents well in advance of their application is imperative for industry planning and particularly if requirements have significantly changed for products categories in either country eg to enable generation of data, implementation of capital and/or resource outlay to upgrade manufacturing sites.

It has also been suggested that during the transition period, it should not be necessary to apply for an exemption eg from new common labelling standards. Rather exemption should be automatic for products supplied prior to the implementation of the new scheme.

Other Selected Issues:

Fees & **Charges/Cost Recovery**

ACSPA's submissions to the Productivity Commission's Inquiry into Cost recovery are attached for the Trans-Tasman's Group reference of our views on these matters. We would reiterate that public health functions and policy development should not be part of the costs recovered from industry.

We would also comment that one of the overall objectives of the Joint Agency should be to improve efficiencies and therefore the overall costs to industry should be decreased.

In addition, we note that the detailed internal organisation of the Joint Agency will be developed further during the implementation planning (and we believe it should reflect the risk management and final definitional structures of medicines and devices broadly - refer also our comments under Governance Issues). Given the peripheral nature of many of our industry's products to the core business of the proposed Joint Agency, the respective costs of eg administration will need to be extremely transparent.

Appendix 4

The headings in Table 9 on page 169 are somewhat confusing. Of great concern however is that the reference to the National Industrial Chemicals Notification & Assessment Scheme (NICNAS) within TGA is substituted in the right hand column to "Joint Agency under agreement with Department of Health and Ageing". Industry is currently proposing improvements to the efficiencies and risk resource management of NICNAS and we therefore seek your urgent clarification of the interpretation of this proposed 'devolution' of NICNAS within the Joint Agency.

Terminology

Within the Discussion Paper, frequently the term therapeutic products is used interchangeably with medicines. This serves as the source of some confusion for our industry sector and makes it exceedingly difficult to comment on the proposals.

For example, Part C Regulatory Requirements for Therapeutic Products, Section 8 entitled Post Market Surveillance of *Medicines* then goes on to discuss adverse reaction monitoring and **pharmacovigilance programmes** for *therapeutic products.* We therefore require clarification of the requirements as they relate to devices (disinfectants) and other therapeutic products.

Similarly, this interchanging of terminology occurs in the recommendations in relation to **advertising.** While we recognise that this is the topic of a separate review (our further comments will be provided on the draft report expected later this month), we would reiterate our position that pre-clearance of advertising may not be relevant to all products defined as therapeutic products in the Joint Agency and in particular devices (refer Part J).

We trust these comments are useful. We look forward to our further dialogue and also receiving copy of the anaylsis being undertaken to consider the costs and benefits of the proposed scheme and Joint Agency.

Please don't hesitate to contact either myself or Geoff MacAlpine, ACSPA's Technical Manager, should you wish further clarification of any issues raised above.

Yours faithfully

Bronwyn Capanna
Executive Director