# DRAFT REPORT OF A REVIEW OF ADVERTISING THERAPEUTIC PRODUCTS IN AUSTRALIA AND NEW ZEALAND (AUGUST 2002)

## RESEARCHED MEDICINES INDUSTRY ASSOCIATION OF NEW ZEALAND SUBMISSION

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### PREAMBLE

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 24 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

### EXECUTIVE SUMMARY

- RMI congratulates the consultants for an extremely thorough review of the issues surrounding the advertising of therapeutic products in Australia and New Zealand.
- RMI broadly supports the recommendations made in the Draft Report.
- RMI supports regulation of advertising in a way that promotes the appropriate and safe use of therapeutic products.
- RMI believes that regulatory controls should be implemented at the lowest possible compliance costs, consistent with the protection of public safety.
- RMI supports the development of a principles-based trans-Tasman code for therapeutic advertising, overseen by a suitably constituted governing board. RMI recommends that the empowering legislation should only include the highest-level principles.
- RMI recommends that a provisional trans-Tasman governing board should be established as soon as possible. Also that the governing board should comprise a majority of members from the therapeutics industry sectors.
- RMI recommends that industry self-regulatory mechanisms for pre-vetting of advertisements should form the core of any advertising regime for advertisements directed to consumers. This should be backed up by

appropriate complaints and appeals mechanisms, with ultimate sanctions for non-compliance resting with the proposed trans-Tasman Therapeutic Goods Agency (TTTGA).

- RMI recommends that the existing industry self-regulatory mechanisms for advertisements directed to health practitioners should continue.

- The pre-vetting, complaints and appeals mechanisms currently operating in New Zealand are commended as a suitable model for the advertising regimes in both New Zealand and Australia.

- RMI recommends that the requirement for pre-approval should be determined by the *claim(s)* being made, rather than the TTTGA product category.

- RMI supports the recommendation for mutual recognition of decisions made by the pre-approval and central complaints bodies in each country.

- RMI recommends that the proposed complaints panel should comprise at least five persons, with a minimum of one member having therapeutic industry expertise.

- RMI recommends that the proposed trans-Tasman appeals body comprise a Chairman with present or past judicial experience, plus two members with experience of reviewing complaints – one from New Zealand and one from Australia.

- For decisions relating to the pre-vetting of advertisements, RMI recommends that the appeals body should only be asked for a ruling after the pre-vetting body in the alternate jurisdiction has provided a "second-opinion".

- RMI recommends that approved labels for Class II (over-the counter) and III (prescription) medicines be excluded from the definition of "advertisement".

- RMI supports consumer representation on the governing body and the development of an effective consumer education campaign following implementation of the proposed changes to therapeutic advertising, but considers that these elements should be funded directly by government.

- RMI concurs with the need to adequately control advertising of complementary healthcare products in New Zealand.

- RMI supports the decision to exclude from the Terms of Reference of the review any policy differences of the New Zealand and Australian governments with respect to advertising of medicines.

- A number of comments and recommendations have been made in the RMI's submission, which, if implemented, would enhance the operation of the proposed trans-Tasman regime for therapeutic advertising.

## SECTION 2. PRESENT REGULATORY ARRANGEMENTS IN AUSTRALIA AND NEW ZEALAND

Included as an annex to this submission are some minor corrections to the paragraphs 117 and 118 in this Section, relating to the RMI Code of Practice Standing Committee and Appeal Committee.

## SECTION 5. THE ADVERTISING CODE AND ASSOCIATED INDUSTRY CODES OF PRACTICE

RMI supports the implementation of a trans-Tasman code for therapeutic advertising, based upon high-level principles and overseen by a governing board. RMI recommends that the empowering legislation should only include the highest-level principles, for example compliance with the law, protection of public safety, social responsibility, etc. In this way, the governing board would be able to set/amend lower-level principles without the need for amendments to legislation in both countries. The governing board could produce guidelines on how the trans-Tasman principles should be administered, but the operating bodies in each country should be free to add further (i.e. more stringent) guidelines should they so choose.

Existing industry Codes of Practice should be allowed to operate alongside the trans-Tasman code, and would provide the best mechanism for resolving competitor complaints. RMI would be proactive in ensuring that its Code of Practice embraced all the principles in the over-arching code, and in trying to achieve consistency with the codes operated by other industry associations across New Zealand and Australia.

## SECTION 6. STREAMLINING ASSESSMENT PROCEDURES FOR PRE-APPROVALS OF ADVERTISEMENTS

The trans-Tasman code could best be effected by self-regulatory advertising regimes operated by industry bodies in Australia and New Zealand. Slightly different systems could operate in each country, according to local needs, however both systems would need to provide consistent and common outcomes.

RMI recommends that industry self-regulatory mechanisms for pre-vetting of advertisements should form the core of any advertising regime for advertisements directed to *consumers*. RMI recommends, however, that the existing self-regulatory mechanisms for advertisements directed to *health practitioners* should continue. Hence, advertisements for prescription medicines directed to health practitioners in New Zealand would not require pre-

approval, but would be covered by the RMI Code of Practice and complaints/appeals mechanisms.

The pre-vetting system currently operating in New Zealand is considered to be a suitable model for the advertising regimes in both jurisdictions, as it incorporates all relevant stakeholders, and is seen to meet the main requirements for a regulatory regime outlined in Section 4 of the Draft Report (i.e. simple, timely, cost-effective, consistent, transparent, consumer focussed, etc.).

The benefits of the New Zealand advertising regime could be retained via the continued operation of the Therapeutic Advertising Pre-vetting Service (TAPS), including Delegated Authorities (DAs), and the Advertising Standards Authority (ASA) complaints and appeals systems. RMI recognises that the robustness of the TAPS/DA processes may have to be further enhanced, in order to accommodate mutual recognition of decisions with Australia.

Although generally supportive of a risk-based approach to the regulation of advertising, the RMI does not support the proposal to use the TTTGA product category (i.e. Class I, II, III) to determine those products that would be captured in the pre-approval system and those products that would be unregulated. As the intrinsic risk (i.e. Class) of a product may bear no relationship to the risks posed by the claims made in relation to that product, RMI instead recommends that the requirement for pre-approval should be determined by the *claim(s)* being made. This would also ensure consistency of application across the full range of therapeutic goods to be regulated by the TTTGA (i.e. prescription and over-the-counter medicines, complementary healthcare products, and medical devices).

In recent years, the New Zealand experience has been that the majority of complaints about therapeutic advertising have arisen from the supposedly lower-risk complementary healthcare product sector[1]. It seems illogical, therefore, to only include Class II and III products in the pre-vetting system, when these products generate a minority of complaints. Such products are generally sold by companies belonging to industry bodies that have demonstrated their ability to adequately police the activities of their members.

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[1] An Evaluation of the Therapeutic Advertising Pre-Vetting Service. Janet Hoek, Massey University, May 2002

## SECTION 7. STREAMLINING PROCESSES FOR HANDLING COMPLAINTS

Given the likely volume of complaints that may be referred to the new complaints panel, RMI considers that a membership of three persons would be insufficient. In order to achieve a satisfactory level of representation and expertise, RMI recommends that the panel should comprise at least five persons, with a minimum of one member having therapeutic industry expertise.

## SECTION 8. APPEALS

RMI concurs that common regulatory outcomes would be delivered across both countries by the establishment of a single trans-Tasman advertising appeals body. Although the Draft Report recommends that the appeals body comprise three members at "judicial level", RMI recommends that the advertising regime could better be served by a Chairman with present or past judicial experience, plus two members with experience of reviewing complaints – one from New Zealand and one from Australia.

Use of the appeals body to review concerns about decisions arising from the pre-approval system would be costly, slow and inefficient. RMI instead recommends that the appeals body not be asked for a ruling until after the pre-vetting body in the other jurisdiction has provided a "second-opinion".

## SECTION 9. CONSISTENCY AND TRANSPARENCY

RMI supports the recommendation for mutual recognition of decisions made by the pre-approval and central complaints bodies in each country.

## SECTION 10. DEFINITIONAL ISSUES

RMI notes the recommendation in the Draft Report that product labels would be considered to fall within the definition of "advertisement". This seems unnecessary for Class II and III therapeutic products, since the labels for these products would already have been reviewed and approved by the TTTGA as part of the registration process. Industry could be faced with additional costs and inconsistency of outcomes if product labelling were to be reviewed as part of any pre-approval or appeals process. RMI therefore recommends that approved labels for Class II and III products be excluded from the definition of advertisement.

## SECTION 11. GOVERNANCE ARRANGEMENTS

RMI recommends that a provisional trans-Tasman governing board should be established as soon as possible, so that it could provide the necessary input into the development of the advertising regime.

RMI strongly recommends that the governing board should comprise a *majority* of members from the therapeutics industry sectors. Not only will the industry fund most of the cost of the regulation of advertising, but it will also operate the self-regulatory procedures. Hence, there are compelling reasons why industry should be involved in the governance arrangements.

For this reason, RMI recommends a slightly different make-up of the governing board, by deleting the last three bullet points under Recommendation 17 and replacing them with the following:

- Four industry representatives from New Zealand – nominated by the prescription medicines industry (RMI), the OTC medicines industry (SMI), the complementary healthcare industry and the media/advertising industry (ANZA).
- Four industry representatives from Australia - nominated by the prescription medicines industry (MA), the OTC medicines industry (ASMI), the complementary healthcare industry (CHC) and the media/advertising industry (APB).
- Two representatives from the centralised complaints body – one from New Zealand (ASA) and one from Australia.

This modification would increase the number of members from 13 to 15, but would provide equitable representation to the major industry stakeholders across the spectrum of products. Importantly, each of the two centralised complaints body will be represented, as a matter of right.

## SECTION 12. IMPACT ANALYSIS (COSTS AND BENEFITS)

RMI is currently collating cost estimates for the present self-regulatory processes for advertising prescription medicines in New Zealand. These will be provided in due course.

RMI supports consumer representation on the governing body and the development of an effective consumer education campaign following implementation of the proposed changes to therapeutic advertising. However, while, industry would generally be happy to cover the necessary costs of education for industry sectors and the costs of the complaints/appeals processes, RMI considers that consumer representation and consumer education should be funded directly by government.

RMI recommends that all references to costs in the final report be stated in NZ$ and/or A$, as appropriate. Where reference is made to fixed costs (e.g. fines), the report should make clear which currency is to be used.

## SECTION 13. LEGAL ISSUES AND LEGISLATION

See separate comments included under the sections above.

## SECTION 14. IMPLEMENTATION PLAN

See separate comments included under the sections above – notably the RMI recommendation that a provisional trans-Tasman governing board should be established as soon as possible, so that it could provide the necessary input into the development of the advertising regime.

## OTHER ISSUES

RMI supports the decision to exclude from the Terms of Reference of the review any *policy* differences of the New Zealand and Australian governments with respect to advertising of medicines. In particular, any regulatory regime should be able to accommodate the New Zealand situation, whereby prescription medicines may be advertised directly to consumers.

RMI concurs with the need to adequately control advertising of complementary healthcare products in New Zealand, particularly advertisements not placed in mainstream media. This could be achieved by effective self-regulation via a complementary healthcare industry code of practice, and/or agreement by that sector would be covered by the requirements of the TAPS pre-approval system.