17 October 2003

Rules of Origin Study
Productivity Commission
PO Box 80
BELCONNEN ACT 2616

Submission to the Research Study on Rules of Origin under the Australia-New Zealand Closer Economic Relations Trade Agreement

This submission to the Research Study on Rules of Origin under the Australia-New Zealand Closer Economic Relations Trade Agreement is from Medicines Australia Inc. Medicines Australia is the national association representing the prescription medicines industry in Australia. Our Member companies represent over 90% of the prescription market and are engaged in the research, development, manufacture, marketing and export of prescription medicines. Medicines Australia and its member companies are committed to enhancing the health of Australians by providing medicines of the highest quality, safety and efficacy, and developing new and improved medicines to which patients should have timely and universal access.

Medicines Australia wishes to bring to the attention of the Productivity Commission the proposed establishment of a joint trans-Tasman regulatory agency for therapeutic goods in order to achieve harmonisation of regulatory requirements under the Trans-Tasman Mutual Recognition Arrangement (TTMRA), which also comes under the umbrella of the Australia-NZ CER Trade Agreement. The proposed joint regulatory agency will replace the Australian Therapeutic Goods Administration and the NZ Medicines and Medical devices Safety Authority (MedSafe) from 1 July 2005 if all legislative changes are achieved as scheduled.

In all the discussions between Medicines Australia and relevant officials from the Department of Health and Ageing and Department of Industry, Tourism and Resources we have emphasised that it would be unacceptable to our industry for parallel importation of goods into Australia from New Zealand to be permitted or facilitated under the proposed new joint regulatory regime. (Parallel importation is the commercial importation of legitimate (non-counterfeit) goods without permission from the licence or patent holder.) However, we have no guarantee that the current legislative requirements under the Commonwealth Therapeutic Goods Act 1989 that in effect prohibit parallel importation will continue to operate under the trans-Tasman regulatory agency.

Our greatest concern about parallel importation is that a sponsor cannot control the supply chain used by parallel importers, meaning that medicines are supplied outside of properly monitored distribution networks, exposing the medicines to potential deterioration or contamination and therefore exposing consumers who take the medicines to greater risk.

It is therefore important to our industry and to Australian consumers that there should not be any weakening of the current rules of origin requirements for determining which goods receive preferential entry into Australia from New Zealand.

Medicines Australia understands that the preferential rules of origin do not directly impact (to allow or prohibit) parallel importation of goods. Our concern is that any weakening of the preferential rules of origin combined with the facilitation of trans-Tasman trade in therapeutic goods through the TTMRA, and potentially the allowance of parallel importation, would have a significant negative effect on the Australian pharmaceutical industry. For example, if therapeutic goods that had undergone minimal or no manufacture in New Zealand enjoyed preferential entry to Australia under the CER and their supply in Australia was also facilitated under the TTMRA and joint regulatory agency arrangements, such products would unfairly compete in the market with products supplied by Australian sponsors. Similarly, parallel importation may be facilitated by weaker rules of origin, rather than having a neutral or negative effect, by making it easier for a parallel importer to obtain product in New Zealand that would qualify for preferential entry to Australia.

Medicines Australia therefore urges that the current preferential rules of origin under the Australia – New Zealand CER should not be weakened to allow preferential trade of products that have not had, as a minimum, the last process of manufacture performed, and at least half of the cost of bringing the product to its finished state expended, in Australia or New Zealand.

Yours sincerely,

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