

RMI Submission on the Proposed Grouping Order

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 18 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.

REPLACEMENT GROUPING

It is stated on page 1 of the proposed Grouping Order that " 'Replacement Grouping' may apply when a minor change is made to an existing product, and the new version is to replace that product. In this case, the product licence holder is expected to cease supply of the existing product before introducing the replacement product to the market".

The RMI supports this process for phasing in of replacement product and believes that the intent of the Authority is to ensure that there is continuity of supply while minimising the period when both the existing and replacement products are in the market/distribution chain.

However, the following sentences in the document state "removing the existing product from the market is required because the product licence number is a unique identifier used to facilitate product recalls and reporting of adverse events. It is, therefore, unacceptable for two "different" products to be in the marketplace with the same product licence number". These statements would appear to imply that prior to introducing replacement product, all existing product would need to be recalled from the market. It has been verbally confirmed to the RMI by the Joint Agency Establishment Group that recall of the existing product is not required.

The RMI recommends that the text of the proposed Grouping Order be amended as follows:

'Replacement Grouping' may apply when a minor change is made to an existing product, and the new version is to ~~the~~ replace that product. In this case, the product licence holder is expected to cease supply of the existing product before introducing the replacement product to the market. ~~Removing the existing product from the market is required because the product licence number is a unique identifier used to facilitate product recalls and reporting of adverse events. It is, therefore, unacceptable for two "different" products to be in the marketplace with the same product licence number.~~

Dated : 14 August 2006