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The Project Manager
Child-Resistant Packaging of Therapeutic Products
c/- Joint Agency Establishment Group
Medsafe
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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.

The RMI supports the safe and quality use of medicines including the use of child-resistant packaging (CRP) as one means to reduce the incidence of accidental poisoning in children.

The criteria outlined in the Draft Order are accepted by the RMI as being appropriate for determining the products which require CRP. Although it is acknowledged that a conservative approach has been taken, the RMI supports the overall objective of achieving an appropriate risk/benefit balance.

The RMI supports the use of Class Entries in the First Schedule as manufacturers/suppliers are clear on any requirement for CRP prior to introducing new products. Similarly, the listing of key substances from within each class will ensure there are no anomalies when named products are used in indications not covered by column 1 - Class Entries.

The Draft Order provides exemptions for some products to be supplied in non-CRP. Specifically, 3 (1) (k) states that the requirements of the Order do not apply where a healthcare professional believes a person would suffer undue hardship through difficulty in opening packaging complying with the requirements of the Order. Currently, some anti-Parkinson's and anti-rheumatic drugs are packaged ex-manufacturer in non-CRP often using packaging which is designed to assist the patient to open the package to obtain their medication. Further, for some products there may be issues such as stability when using blister packaging and re-closable CRP would not be appropriate for these patient groups.

The RMI, therefore, strongly recommends that there is a process whereby exemptions from CRP can be sought and granted on named (brand) products.

With regard to the packaging itself, it was noted in the Draft Order that "...the robustness and effectiveness of blister or foil strip packaging as a child-barrier needs to be increased...". Further it was suggested that in the future mandatory compliance with a Standard may be considered.

Pharmaceutical manufacture and supply is an international industry and the combined Australia-New Zealand market makes up less than 2% of the world market. Thus, for reasons of practicality - many products are supplied in "global" packaging - and cost-effectiveness, **the RMI strongly recommends that any future performance Standard(s) selected for child resistant packaging are international and do not include any additional local specifications.**

The RMI also strongly recommends that the transition period be 5 years to ensure a suitable safety period in the event that any manufacturing/stability issues may arise.

Yours sincerely

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