

## **RMI Submission on the Draft General Requirements for the Labelling of Medicines Australia New Zealand Therapeutic Products**

### **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.

### **SUBMISSION**

*7 (3) Where intermediate packaging (if any) is opaque, then the label on the intermediate packaging must include:*

- (a) the product name;*
- (b) the name(s) of all active ingredients in the medicine;*
- (c) the quantity or proportion of all active ingredients in the medicine'*
- (d) the batch number of the medicine preceded by the batch number prefix;*
- (e) the expiry date of the medicine preceded by the expiry date prefix; and*
- (f) the name or registered trademark of the sponsor of the medicine.*

**The RMI supports the inclusion and extent of the proposed labelling requirements for opaque intermediate packaging.**

**The RMI recommends that the Expert Committee includes a definition of "opaque intermediate packaging" in the Interpretation section of the Order.**

**The RMI also recommends that the definition of "opaque intermediate packaging" includes intermediate packaging where any surface of is opaque. For example, packaging which is paper/foil on one side and transparent on the other should be considered opaque as part of the container label may be obscured.**

*8 Particulars to be included on a main label*

*8(5)Where the product is a Class 2 medicine that can only be supplied in accordance with the individual proscription of a health professional authorised under relevant local legislation to prescribe, or is a medicine for injection:*

- (a)the name of every active ingredient, together with the quantity or proportion of every active ingredient , must be prominently displayed adjacent to, or immediately under the product name on the*

*main label, in a letter height at least half that used for the product name, but in any case, not less than 2 millimetres*

*except that:*

*(b) where there are five or more active ingredients in the medicine is shall be sufficient compliance with this subclause if the names of every ingredient.....are included on a side panel or side label or on a rear panel of rear label.....*

Please find attached to this submission an example of an existing primary package for a very small injection which would be compliant under this subclause. From this example, however, it can be seen that including a fourth active on the main label would be very difficult to achieve, if indeed it is possible at all.

**The RMI therefore, recommends that where there is insufficient room to list all the active ingredients on the main label of the primary packaging for very small injections and very small containers, it will be considered sufficient compliance with this subclause to list the active ingredients on the side or rear of the packaging.**

The RMI accepts a minimum font size of 2mm for the active ingredients. However, the RMI does not support the requirement in subclause 8(5) (a) for the letter height to be at least half that used for the product name.

The value of a unique product name to unequivocally identify a product is recognised by the Committee in the concessions for very small injections and very small containers. Thus, a product name which is more than twice the height of the active ingredients can be advantageous from a safety perspective in the unequivocal identification of a product.

**The RMI recommends removing the requirement for the letter height of the active ingredients to be at least half that of the product name.**

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Contact:

Debbie Wyber

Manager, Technical & Scientific Affairs

Researched Medicines Industry Association

Level 1, Perpetual Trust House, 111 Customhouse Quay

PO Box 10447, Wellington

Ph 04 499 4277

Fax 04 499 4276

Email [dwyber@rmianz.co.nz](mailto:dwyber@rmianz.co.nz)