

**DRAFT LABELLING REQUIREMENTS FOR MEDICINES UNDER A JOINT
AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY**

AND

**DRAFT BEST PRACTICE GUIDELINE ON PRESCRIPTION MEDICINE
LABELLING**

**RESEARCHED MEDICINES INDUSTRY ASSOCIATION OF NEW ZEALAND
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Submission on behalf of the Researched Medicines Industry Association

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DRAFT LABELLING REQUIREMENTS FOR MEDICINES UNDER A JOINT AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY

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 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.

ISSUES RE TRANSITION TO THE NEW LABELLING REQUIREMENTS

In the covering letter to stakeholders, from the Executive Director of the Joint Agency Establishment Group, it states "it is anticipated that this standard would become effective from the commencement of the new joint agency, with a transition period of up to three years for sponsors to comply with the regulatory changes....including compliance with the new labelling requirements".

While it may be possible to have new labelling approved by the agency within that time frame, as part of the application for a dual country licence, the new labelling cannot necessarily be introduced into the market during this 3-year transition period. The RMI proposes that the phase-in period for new labelling be extended beyond the proposed three years by at least 12 months for high volume products and 24 months for low volume products.

It is not practical or possible for companies to meet an earlier deadline for the physical introduction of new labelling for the following reasons:

- Resource constraints – it has been estimated by one company, that under the proposed time frames, 50% of their global artwork resources would be required to meet the demands of the Trans-Tasman market.
- Labelling cannot be printed until the dual licence has been issued to ensure that the labelling accurately reflects the licence details, including the unique identifier.
- There are potentially significant costs to industry if stocks of labelling material, and/or labelled product, need to be discarded or relabelled.

DRAFT LABELLING REQUIREMENTS

In providing feedback on the draft Order, the RMI notes that there are a number of details that are yet to be finalised or consulted on including some of the definitions, the required advisory statements for labels and the provisions allowing exemptions. Thus, further comment may be provided by the RMI on the labelling Order as these points are finalised.

1. INTRODUCTION

Paragraph 1: "Medicine labels also include other information not required by this Order, but which may be required by other legislation...". Currently, the Australian Customs Act "country of origin" labelling requirements include prescription medicines. Licensed pharmaceuticals should be exempted from this requirement as the information is provided as part of the licensing requirements and it confers additional compliance costs without contributing to the quality use of medicines.

5. INTERPRETATION

'Container', 'primary pack': The definition of primary pack used in the Order is confusing compared with common practice in New Zealand. It is, therefore, recommended that 'container' and 'primary pack' be replaced with 'primary pack' and 'secondary pack', respectively.

Alternatively, 'immediate' and 'outer' pack, could be used. This terminology is consistent with that used in the EU, and also with the joint agency's Code of Good Manufacturing Practice for Medicinal Products.

'Date of Manufacture': The definition of 'date of manufacture' for a medicine other than a biological product is not consistent with either the EU/EMA or FDA guidelines and is not consistent with international best practice. The RMI recommends, therefore, the definition of 'date of manufacture' as being the "date that the first step is performed involving combining the active ingredient with other ingredients. For medicinal products consisting of a single active ingredient filled into a container, the initial date of the filling operation is taken as the date of manufacture".

'Signal words': the format of signal words will be specified in the scheduling standard. The retention of options, such as POM, is considered important by industry - allowing flexibility in the use of packaging across more than one country/regulatory authority

2.APPLICATION:

2. (1) Reference is made in this clause to the possibility of obtaining from the Managing Director “an exemption from compliance with this standard” in accordance with the provisions in the Rules. The Rules have yet to be finalised or consulted on.

The RMI recommends that exemption from the requirements of the labelling Order be retained as per the existing Medsafe regulatory guidelines, as follows:

Exemptions are granted on a case-by-case basis and may be granted when:

- Low sales volume for the product (i.e. 3000 or less units per year, or the sponsor can justify a higher limit) mean that the cost of amending the labelling would not be recoverable **or**
- Temporary, unforeseen stock shortages require the importation of stock with non-compliant labelling providing the non-compliance does not adversely impact on safe use of the product or cause confusion or misuse.

7. PARTICULARS TO BE INCLUDED ON A LABEL; 8 . PARTICULARS TO BE INCLUDED ON A MAIN LABEL

It is permitted in section 7(1)(k) that where there is insufficient space on the label of the container or on the primary pack to include directions for use these may be set out instead on a leaflet inserted in the primary pack.

Notwithstanding the qualifications in Section 9, the RMI strongly recommends that the pack insert be generally considered to be part of the labelling for a number of the mandatory requirements, as appropriate, where these cannot be incorporated in the label or where the inclusion of such requirements in a leaflet would improve patient safety or quality use of the medicine.

Section 7 (1) (p) and Section 8(2) require the “unique identifier” (where applicable) to be included on the label or labels and specifically the main label. What is the purpose of including the unique identifier on the main/label?

8. PARTICULARS TO BE INCLUDED ON A MAIN LABEL

8.(3)(a) : proposes that for prescription medicines, controlled drugs and medicines for injection, the active ingredients must be in a letter height at least half that used for the product name and not less than 2millimetres.

The RMI supports requiring a minimum letter height for active ingredients to assist in reducing dispensing errors but does not support the requirement for the product name to be no more than twice the height of the active ingredients. Prominent product names also assist in reducing dispensing errors especially where prescriptions are written using product names. Another example of the value of a prominent product name is where there are generic brands available of drugs with a narrow therapeutic window. In such cases, the product name is the important identifier.

9(12) STARTER PACKS:

The draft Order requires that the label on Starter Packs include “a space to allow addition of at least the following dispensing details: patient’s name, prescriber’s name, directions for use, and date of supply”.

Starter packs are frequently small dimension packs and to include the aforementioned space may require a larger outer carton (AKA “primary pack”) that will increase production and shipping costs.

10 (5) PERMITTED STATEMENTS OF STORAGE CONDITIONS:

With a view to the joint agency’s objective of aligning with international best practice, the RMI recommends alignment of the draft Order’s permitted statement of storage conditions with those of the EMEA.

The EMEA required labelling statements include, for example, either “ do not store above 30°C” or “store below 30°C”. Thus, the RMI recommends that the Permitted Statements in the joint agency labelling Order be in line with the EMEA either verbatim or as a composite phrase, e.g. “Store at or below 30°C”.

DRAFT BEST PRACTICE GUIDELINE ON PRESCRIPTION MEDICINE LABELLING

The Best Practice Guidelines are designed to assist sponsors in the design of labels for prescription medicines to minimise the risk of prescribing and dispensing errors. The Guidelines while referenced in the Order are not included in the mandatory aspects of the Order but are complementary to them.

In consideration of the objectives and role of the Guidelines, the RMI raises the following points for consideration by the Expert Committee.

1. Space for the Pharmacist's Label

Requiring a clear space for the pharmacist's label is not always feasible depending on the size of the pack and mandatory information requirements. This is especially true of small volume products e.g. eye drops and while the Guidelines suggest affixing a cardboard backboard, this has cost implications for packaging, shipping and storage.

Further, one company has strived to differentiate products within a therapeutic class through differentiated "faces". This allows the different brands to be visually recognised from the warehouse to the patient. Introducing a clear space for the pharmacist's label could lead to similarity in appearance.

4. Barcode

The RMI supports the optional inclusion of barcodes on labels to assist in improving patient safety and reducing dispensing errors.

Consideration should be given to harmonising bar-coding across New Zealand and Australia.

9. Specific Australian Issues

Potassium labelling: The point has been raised that colour coding potentially encourages the user to rely on the colour coding at the expense of reading the label. This is of greatest concern when the product can have an immediate adverse effect if used in error.

If colour coding is to be used, the risk of such an administration error occurring will be minimised by restricting the use of the same or similar colour coding to a single product.