MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

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Dear John

TGA Medicine Labelling and Packaging Review

As discussed at the TTSOG meeting in June, Medsafe and the Ministry of Health policy team have reviewed the proposals set out in the *TGA Medicine Labelling and Packaging Review* consultation paper published in May this year.

In undertaking the review, we have focussed on how we would see the proposals fitting into the future ANZTPA regulatory scheme. Our comments are set out in the attached table. We are happy for you to decide whether or not you wish to treat this letter and attachment as a formal submission on the review.

We would be pleased to assist with analysis of submissions on the review if that would be helpful. We would also be very keen to be involved in the process of considering stakeholder comment and finalising the detail of the changes to labelling and packaging requirements that will be carried forward.

We look forward to providing input into further stages of the review as it progresses.

Yours faithfully

Stewart Jessamine
Group Manager Medsafe

NZ comments on TGA Medicine Labelling and Packaging Review

1. Prominence of active ingredients on medicine labels

We support the overall intent of the proposals relating to the prominence of active ingredient names on labels. However, we have the following concerns about specific elements of the proposals:

(i) We question what additional benefit would come from the requirement in 1.1 for complete alignment of the brand name and ingredient names. We note that in the example provided, the ingredient names are aligned with the company name, rather than the brand name. We would support requiring the ingredient names to be directly underneath the brand name, but consider the requirement for left alignment of the ingredient names to be unnecessarily rigid.

(ii) Proposal 1.2.2 specifies that the font size used for the names of the active ingredients must be 100% of the font size used for the brand name. We consider the 100% requirement to be unnecessary, but would support a requirement for the font size used for active ingredients to be 'not less than x% of the font size used for the brand name'. An appropriate figure would be in the order of 70%.

(iii) We have concerns about the proposed requirement in 1.3 for the 'most abundant ingredients' to be listed on the main label. This could mean that a potent ingredient present in a small amount is not listed on the main label even though it is the most therapeutically significant ingredient in the product.

(iv) The requirement in 1.6 and 1.7 for the expression 'Consult your doctor or pharmacist...' to be included in the paracetamol and ibuprofen warning statements would be problematic for New Zealand where not all prescribers are doctors. "Consult your prescriber or pharmacist....' would be more appropriate. Providing this flexibility could be achieved by allowing use of 'words of a similar meaning'.

2. No section 2 in Consultation Paper

3. Look-alike sound-alike names and look-alike packaging

We support the overall intent of the proposals relating to look-alike sound-alike names and look-alike packaging. However, we have the following concerns about specific elements of the proposals:

(i) It is proposed in 3.1 that sponsors of new medicines are required to provide evidence of risk assessment of the proposed labelling and packaging. Care needs to be taken to ensure that the associated compliance costs do not discourage sponsors from marketing their products in the relatively small Australia/New Zealand market.

(ii) While agreeing that it would be ideal to not allow the same medicine to be

marketed under different brand name for various subsets of indications, we feel this is too idealistic given current branding approaches in the NZ and Australian markets and other developed countries. We query whether this practice creates a real patient safety issue provided it is underpinned by requirements such as those in current UK and Australian guidance.

4. Standardised Information Format: the Medicine Information Box

We support the overall intent of the proposals relating to the Medicine Information Box. However, we have the following concerns about specific elements of the proposals:

(i) Until recently, New Zealand required the label on an over-the counter medicine to have certain information grouped together in a 'Consumer Information Panel. This requirement was removed because it was not consistent with requirements in other major markets.

(ii) Such a requirement could create a situation where it is necessary to grant exemptions from the 'Medicine Information Box' requirement in order to ensure consumers have access to the full range of medicines available in other countries. Such an exemption mechanism is administratively cumbersome.

5. Dispensing label space

We support the overall intent of the proposals relating to the dispensing label space on prescription medicine labels.

6. Blister Strip Labelling

We support the overall intent of the proposals relating to blister strip labelling. However, we are concerned about the proposal for the batch number and expiry date to be with the name and strength information 'in a single location'. Imposing such a requirement would mean that the common practice of embossing the batch number and expiry date at one end of the blister strip would not be acceptable. Compliance with the proposed new approach would necessitate, for many companies, pre-printing of batch numbering and expiry date on the foil (which would not be practical), or retooling to enable the batch number and expiry date to be presented multiple times in the same location as the name and strength of the product.

7. Small containers

We support the overall intent of the proposals relating to small containers. However, we have the following concerns about specific elements of the proposals:

(i) We query the requirement in 7.1 for a package insert in situations where a small container is enclosed in a primary package that has a fully compliant label. The labelling of such a product would, through the labelling of the

primary package, meet the same requirements as other product labels Inclusion of a package insert should not then be mandatory.

(ii) The requirement in 7.2 for the label of a multidose ophthalmic preparation to state that the medicine should not be used for more than four weeks after opening should be made more flexible to cater for eye drops that are intended to be used for a longer period.

8. Pack inserts

We support the proposals relating to pack inserts.

9. Labels and packaging advisory committee

We do not support the concept of a Labels and Packaging Advisory Committee as we consider this would be an administratively burdensome, expensive and inefficient mechanism for making determinations relating to packaging and labelling of products. We would expect it would be possible for a small group of experienced staff with appropriate expertise to provide advice on labelling and packaging where issues arise that are not able to be dealt with by evaluators.

General comments

We would support changes to labelling and packaging requirements where these are consistent with requirements in other major markets. We would, however, be concerned if the changes meant that Australia/New Zealand-specific labelling was required, since the Australia/New Zealand market is relatively small and manufacturers may choose not to supply product on economic grounds.

We support the use of consumer testing in providing evidence of the safety and effectiveness of labelling that goes outside the boundaries set in the labelling rule book. We do not agree however that consumer testing should be mandated for every label. Instead there should be a prescribed "safe harbour" approach set out in the labelling rules so that companies who wish to avoid the compliance costs associated with innovation in label design and the associated costs of consumer testing can choose this path.

We have not assessed whether the proposals are practical for all container / medicine combinations and would expect manufacturers and sponsors to comment on whether space constraints are an issue in their submissions.