Medicines New Zealand Submission on International Harmonisation of Ingredient Names (IHIN)

15 July 2013

International Harmonisation of Ingredient Names
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

By email to: askmedsafe@moh.govt.nz

Dear Susan

Submission on International Harmonisation of Ingredient Names

Thank you for the opportunity to comment on this proposal.

Medicines New Zealand is in the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines and vaccines. A central objective of Medicines New Zealand is to promote the benefits of a strong research based industry in New Zealand.

Although this consultation has been initiated by the TGA and relates to the regulatory system in Australia, we are pleased that ANZTPA has been acknowledged as a likely endpoint.

Since the activities of Medicines New Zealand members are focused on prescription medicines, this submission concentrates on the proposal as it relates to prescription medicines and vaccines.

Please do not hesitate to contact me if you have further queries with regards to our submission.

Yours sincerely

Philippa Davies
Senior Advisor - Science and Technical

Consultation Submission Cover Sheet

Submission on International Harmonisation of Ingredient Names (IHIN)	
Name and designation	Philippa Davies, Senior Advisor – Science and Technical
Company/organisation name and address	Medicines New Zealand , Level 8, 86-90 Lambton Quay , PO Box 10-447, Wellington 6143
Contact phone number and email address	(04) 499 1159 Philippa.davies@medicinesnz.co.nz
I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes☒No
I would like my name to be removed from all documents prior to publication and for my name not to be included within the list of submissions on the Medsafe website.	☐ Yes ☒No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, an organisation that is based in:		
☒ New Zealand	☐ Australia	☐ Australia and New Zealand

I am, or I represent, a: *(tick all that apply)*			
☐ Importer	☐ Manufacturer	☐ Supplier	☐ Sponsor
☐ Government	☐ Researcher	☐ Professional body	☒ Industry organisation
☐ Consumer organisation	☐ Member of the public	☐ Institution (e.g. university, hospital)	
☐ Regulatory affairs consultant	☐ Laboratory professional		
☐ Health professional – *please indicate type of practice*:			
☐ Other - *please specify*:			

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We have responded to question 1-4, and 6-8 of the consultation paper.

1. *Looking at the lists of proposed ingredient name changes, do you foresee any specific concerns or benefits as a result of any of the proposed names changes?*

Medicines New Zealand supports international harmonisation of non-proprietary names (INNs) and INN policy because of the benefits of international recognition of ingredient names by health care professionals. Another reason is because Medsafe already supports INN nomenclature so as a result there will likely be little impact on medicines currently approved in NZ.

2. *What do you think about the proposal to include both the current approved name and the proposed new name (dual labelling) for substances of high clinical significance?*

Our only concern about the dual labelling is that the list of ingredients to be dual labelled affects more products than in the UK for example (which only includes adrenalin, noradrenalin and lignocaine), with the result that more products will require dual labelling for the Australian/NZ market compared to other markets. We want to avoid the situation where some INN labelled products in New Zealand must be dual labelled with the BP name, only for it to be removed again after a transition period to a single harmonised ingredient name.

3. Do you agree that harmonising the names of ingredients with international practice will be beneficial?

Yes, because it will bring Australia and New Zealand in line with international best practice.

4. Is the proposed period for using dual labelling appropriate?

Yes. There should also be a transition period from dual labelling to enable stock in the supply chain to be sold through before reverting to the proposed new name. A transition period from dual labelling is recommended as 5 years to allow for products with low stock turns.

We note that there was an associated prescriber and patient education campaign on the name changes in UK. This should be considered for Australia and New Zealand.

6. Do you agree that harmonising the names of ingredients with international practice will be beneficial?

Same as for question 3.

7. Specifically, will the name changes make preparing labels and other documents for the Australian market easier, in terms of international consistency?

There will be an impact for manufacturers associated with this proposal.

For products originating from the global supply chain and labelling not shared with Australia, a labelling change would be required for New Zealand and a CMN. The timeline for a labelling

change varies depending on the country of origin, manufacturing and printing times. Following the labelling changes, there would be additional time required for a CMN approval. The impact is the time and cost to make the labelling change at the manufacturer level, and the time and fee for a CMN application in New Zealand.

For packs shared with Australia, the ingredient name change would occur in Australia, and there would be no other change for NZ in terms of labelling changes at the manufacturer level. The timeline for a labelling change would be the time for the labelling change in Australia and the time required for a CMN approval. The impact is the time and cost to make the labelling change at the manufacturer level, and the time and fee for a CMN application in New Zealand.

8. Do you agree that the proposed transitional period is sufficient to ensure associated costs, such as printing new labels, could be met through business-as-usual activities?

Regarding transitional periods our members have commented that the transition to the proposed new names should be extended to 5 years to allow for the time to make the changes outlined in question 7.

Whilst we understand that the review of labelling and packaging is outside the scope of this consultation, in order to reduce costs to our members, we consider that all proposed changes to labelling (including ingredient name changes, labelling changes as a result of the labelling packaging review, changes required due to ANZTPA) and packaging must occur at the same time. In order to streamline the process we recommend that ingredient name changes are notified as a self-assessable change.

We also recommend that Australia and New Zealand waive fees for notifying ingredient name changes only, as a result of this proposal. This is in line with the approach taken in the UK.