Medicines New Zealand Submission on Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods.

17 June 2013

Management and Co-ordination Section
Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

By email to: complianceconsultation@tga.gov.au

Submission on Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods.

Thank you for the opportunity to comment on this consultation.

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, the outcome of the review is very likely to be carried through to ANZTPA hence Medicines New Zealand is making this submission on behalf of its member companies.

Medicines New Zealand remains concerned that these projects are not being conducted as ANZTPA projects as we consider that changes made at a local level must align with the likely ANZTPA model. We strongly request that projects involving significant review of regulatory policy or procedures are conducted as ANZTPA projects requiring joint TGA/Medsafe consultation (this includes having New Zealand stakeholders on working groups).

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

Yours sincerely

Kevin Sheehy (MB ChB)
General Manager

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TGA consultation submission

Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods	
Name and designation	Kevin Sheehy, General Manager
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Contact phone number and email address	+64 4 494 1154 Kevin.Sheehy@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* (see members list)
☐ 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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***Medicines New Zealand Member Companies**

Abbott
AbbVie
AstraZeneca Ltd
Bayer HealthCare Ltd
bioCSL (NZ) Ltd
Biogen Idec NZ
Boehringer Ingelheim NZ Ltd
Bristol-Myers Squibb
GlaxoSmithKline
Healthcare Logistics
IMS Health (NZ) Ltd
Janssen
Leo Pharma Ltd
Merck Sharp and Dohme
Mundipharma NZ Ltd
Novartis NZ Ltd
Pfizer
Roche
Quintiles Pty Ltd
Sanofi
Vifor Pharma Pty Ltd

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Our comments address the questions included in the Content of Submissions on page 5 and 6 of the consultation paper.

• *whether or not you support the idea of a new-to-market risk communication scheme,*

Medicines New Zealand is commenting on this scheme from the perspective of this scheme being carried through to ANZTPA.

When exploring a new risk communication scheme we would support such a scheme in principle, provided:

- Australia/NZ follows the EMA risk monitoring scheme that has been tested and found to be effective, rather than create a new scheme that is untested.

and

- Medsafe or the joint regulator has the capacity to monitor the scheme under ANZTPA. This is in order to justify the time and additional cost required by our member companies to comply with the additional requirements.

• *the potential value and uses of a new-to-market risk communication scheme,*

As above, there needs to be evidence that similar schemes are of value.

• *how a new-to-market risk communication scheme might best be designed, promoted and evaluated, and*

Again, when exploring a new-to-market risk communication scheme we would support in principle a model that has been tested and found to be effective, rather than create a new model.

Medicines New Zealand would like to be included in any working groups that are set up to develop the proposed model.

• *how a new-to-market risk communication scheme will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.*

From a manufacturer's point of view there would be additional costs and an impact on the global supply chain. There would be impacts on packaging, labelling, CMI, PI, and promotional materials which would need to be factored into the manufacturing costs. We also consider there will be regulator costs to maintain the scheme and these costs would inevitability be passed onto the manufacturers under the full cost recovery model proposed under ANZTPA.

Due to time constraints to submit our comments on this proposal, it is not possible to provide more detailed information on the costs and benefits to manufacturers at this time.

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If the scheme was introduced into the TGA and not Medsafe, there are a number of impacts on our companies in New Zealand. If the black triangle was used on harmonised packaging and labelling, it may be confusing for health care practitioners (HCPs) and consumers as they will not know what it means.

Harmonising product information, labelling, and packaging between Australia and New Zealand is more efficient for our members. Whilst we are aware of other Australian specific information such as the ARTG number on harmonised product packaging and labelling, we would like assurance that the appearance of the black triangle would not be problematic for HCPs and consumers in New Zealand.