9 April 2013

Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

By email to: medsafeadrquery@moh.govt.nz

Dear Susan

Submission on the Trans-Tasman Early Warning System of Safety Concerns with Medicines and Medical Devices

Thank you for the opportunity to comment on the early warning system.

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

Medicines New Zealand supports safe medicines use and supports in principle the proposed warning system but with tightened engagement with sponsors. Since the activities of Medicines New Zealand members are focused on prescription medicines, this submission concentrates on the proposal as it relates to medicines, and not medical devices.

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

Kevin Sheehy (MB ChB)
General Manager

Medsafe is seeking comments on:

The proposed Early Warning System webpages eg

- Does the content describe the Early Warning System in sufficient detail?

- Is the content understandable?

- Was the layout of information within the webpages and within the Medsafe website easy to follow?

- Are there any changes you would like to suggest?

Medicines New Zealand notes that the communications will be country specific and may differ reflecting different legislative requirements and availability between countries. Where there are differences in the communications, it would be helpful if Medsafe and the TGA inserted some explanation of the reason for the differences on their respective websites. This is to prevent any confusion at consumer and HCP level that may arise as a result of the different communications.

The presentation of the hypothetical examples eg

- Did the types of information covered in the monitoring communications meet your expectations?

- Did the types of information covered in the alert communications meet your expectations?

- Did you find the level of detail in the monitoring communications and the alert communications suitable?

- Did you find the information you were interested in?

- Are there any changes you would like to suggest?

We have no comments on the content of the communications however we do support tightening engagement with sponsors. Please see our comments regarding sponsor engagement in the Additional Comments section.

The proposed communication channels eg

- Do you agree with the proposed channels to be used for communicating monitoring communications?

- Do you agree with the proposed channels to be used for communicating alert communications?

- Are there alternative communications channels Medsafe should use when issuing monitoring communications and/or alert communications?

PHARMAC funded section 29 medicines. Whilst there are benefits of increased scrutiny of potential safety concerns with PHARMAC funded section 29 medicines, given the constraints around the use of unapproved medicines we recommend in the first instance that Medsafe notifies prescribers using the prescriber details supplied on the section 29 notification form.

Additional Comments

Medicines New Zealand considers that sponsor engagement needs to be tightened throughout the Early Warning System process.

Initial Assessment/Risk Analysis and Signal Investigation/Assessment.

Whilst the proposal states that sponsors/manufacturers would be informed of communications, to avoid doubt we recommend that the process flow diagram be amended to show when that engagement would occur. If no potential safety concerns are identified, we do not consider there needs to be sponsor engagement, however if a potential safety concern has been identified the TGA and Medsafe must engage with sponsors following the initial assessment/risk stage and signal investigation/assessment stage. Therefore we recommend the "If required" statements in the process flow diagram be amended to "Yes" or "No" process flows depending on the outcome of the initial assessment/risk analysis, and the signal investigation/assessment. The reason for engaging with sponsors at these times is that they should be provided with early warning of potential safety concerns, be provided with an opportunity to provide further information, and have input into any communication released via any communication channel.

In a similar way, we recommend that the process flow diagram at the Alert Communication stage be amended to show sponsor engagement.

Decision criteria

We note that the decision criteria includes if there is likely to be interest in the potential safety concern from consumers, health professionals, government or media. There will need to be a balance struck between communicating potential safety concerns and avoiding unwarranted concerns which may result in consumers discontinuing their medications.