

## **Medsafe is seeking comments on:**

### *The proposed Early Warning System webpages eg*

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

Yes

- Is the content understandable?

The actual webpages seem okay, but the explanation in the consultation document is not easy to read and should be addressed if this will form the basis of any website link to further elaboration of the system.

The Discussion Document's criteria setting out the terms under which each action option will apply is laboriously painful to read (i.e. and "...." or .. "and at least one of the following") and consequently not easy to understand when they may be invoked. This reads more like a legal document rather than a user friendly explanation.

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

These seem reasonable, but the acid test will be with real signals and the degree to which readers comprehend the message

- Are there any changes you would like to suggest?

YES

#### Glossary of terms (page 14 – CARM):

This definition only refers to CARM function to "... collect reports of suspected adverse reactions...". The term "collect" alone grossly understates the actual function and work performed in the Centre and its function. This should read: "... to receive, assess and monitor reports of suspected adverse reactions to medicines and vaccines in New Zealand.

### *The presentation of the hypothetical examples eg*

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

These seem reasonable, but the acid test will be with real signals and the degree to which readers comprehend the message

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

As above

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

As above

- Did you find the information you were interested in?

As above

- Are there any changes you would like to suggest?

### *The proposed communication channels e.g.*

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

There is no immediately apparent section of the Discussion document that specifically addresses "communication channels". There is reference to the communication being posted on the respective Regulator's websites which is one "channel" but there is no discussion on other options. There is reference to location and format of publications contained in an Attachment 1 (page 12), but this only involves the website

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

As above

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

In the current age, it would be reasonable to see some discussion on additional channels of communication that may be appropriate depending on the nature of the signal and/or content. A diversity of widely available and utilised media exist that may serve to support and direct readers to the webpage. In this move to a new era and Agency there should be consideration and exploration of the use of these channels. Examples of other channels include:

- Facebook/Twitter pages content to at the very least alert and direct users to new messages on the website as the primary source.
- Mirrored links on professional organisation websites and email list servers e.g. Professional Colleges / Societies / Organisations and Newsletters
- Professional media (NZ Doctor, BPAC journal etc.)

#### *Additional Comments*

I was surprised that there was no reference to evaluation and/or impact of the proposed methods, strategies, and in particular channels and content/format that will be used once the system is in place. Feedback from readers and intended recipients must surely form an essential part of any new communication strategy. Taking account of this type of feedback from targeted surveys will help to inform and hone the not only the appropriateness and nature of the content, but also help to tailor the suite of channels and techniques to best advantage for both the needs of regulator and audience. This is an opportunity for the new Joint Agency in the making to lead the pharmacovigilance world in striving for the most optimal communication of Early Warning messages and not harnessing this avenue is a lost opportunity.