

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? *Yes*
- Was the layout of information within the webpages and within the Medsafe website easy to follow? *Yes*
- Are there any changes you would like to suggest? *No*

The presentation of the hypothetical examples eg

- Did the types of information covered in the monitoring communications meet your expectations?
Yes, recognising these are hypothetical examples, not reconfigured examples of previous alerts
- Did the types of information covered in the alert communications meet your expectations?
Yes, recognising these are hypothetical examples, not reconfigured examples of previous alerts
- Did you find the level of detail in the monitoring communications and the alert communications suitable?
Yes, recognising these are hypothetical examples, not reconfigured examples of previous alerts
- Did you find the information you were interested in? *Yes*
- Are there any changes you would like to suggest? *See 'Additional Comments' below*

The proposed communication channels eg

- Do you agree with the proposed channels to be used for communicating monitoring communications? *Yes*
- Do you agree with the proposed channels to be used for communicating alert communications? *Yes*
- Are there alternative communications channels Medsafe should use when issuing monitoring communications and/or alert communications? *For serious alerts, Medsafe may wish to consider the use of social media resources which can provide a rapid means of communication.*

Additional Comments

The Pharmaceutical Society **supports** the objectives in developing an aligned early warning system of potential safety concerns around therapeutic products. We believe the proposed webpages, presentation of the hypothetical examples and proposed communication channels outlined in the consultation describe an informative process with relevant information and appropriate means of communication. We note that the consultation does not outline recall processes, but is focussed on the mechanisms for an early warning system related to potential safety concerns. Therefore this submission does not make any comment on current or proposed recall processes.

Consumers often hear media reports of a safety issue with a medicine they currently take and then approach pharmacists for advice. A lack of credible information providing context and significance to the report, along with guidance for managing the concern for individuals can be a source of extreme frustration for pharmacists in managing these requests. We would hope that the processes outlined in the consultation assist in resolving some of the issues faced by front-line health professionals in addressing the concerns of patients, and provide sufficient information to assist ongoing management decisions.

With respect to communicating concerns, particularly to the media, we would encourage Medsafe to include links directly to the specific alert information on the Warning System webpages. This will allow consumers and health professionals to quickly access the most current advice or information without having to navigate through the whole website. This would be of most importance for Alert communications.

We would also encourage communications aimed at consumers and the media to provide as much explanation as possible (in layman's terms) of the context and significance of the alert. Despite many recent media reports related to medication safety stating patients should not to stop taking the medication without consulting their doctor or pharmacist, patients still discontinue out of fear. Providing some explanation of what the information in the alert means and potential significance of the risks involved, we hope will go towards allaying immediate fears for personal safety. An example could be, where possible and/or relevant, to have an explanation of absolute risk when media reports frequently use relevant risk. This will help offer some context of risk.