

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?

The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to briefly comment on the Therapeutic Goods Administration (TGA) and Med safe discussion paper on the Trans-Tasman Early Warning system – how the process will work in Australia and New Zealand.

We agree with the intent of the Early Warning system and believe that this will aid to safeguard public health and safety with medicines and medical devices.

We seek clarification in regard to the Early warning system (landing page 18) information on the adverse events to medicines and medical devices. In particular we suggest that stipulating General Practitioners as the only practitioners who can submit adverse events via the online reporting tool available in patient management software would be inconsistent with New Zealand legislation and regulation. The prescribing continuum already includes other practitioners such as midwives and dentists and will continue to be extended beyond medicine to encompass Nurse Practitioners, clinical nurse specialists, pharmacists, podiatrists etc. We recommend that online access to submit a report includes regulated health professionals whose scope of practice includes prescribing.

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?

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?

Additional Comments