



Australian Government
Department of Health and Ageing

Appendix to the PROTECT Annex to the Australian Health Management Plan for Pandemic Influenza

21 September 2009

Appendix 4 – Pandemic Vaccine Adverse Event Reporting

Vaccine safety monitoring at all levels will be important for the pandemic (H1N1) 2009 vaccination program. Vaccine safety monitoring is a shared responsibility among the Australian government, State and Territory health departments, the vaccine manufacturer CSL, immunisation providers and other health care workers, and the general public.

When influenza vaccines are administered according to their indication and usage information they are safe. However vaccines, like any medical product, carry some risks. Clinical studies on the safety profile of the Panvax® H1N1 vaccine have shown that the frequency of side effects is similar to seasonal influenza vaccines. Serious adverse events after seasonal influenza vaccination are uncommon and it is reasonable to assume they will also be uncommon following vaccination with the Panvax® H1N1 vaccine.

Adverse events following influenza vaccination may be coincidental or causally related to the vaccine. While minor local reactions and symptoms are relatively commonly reported following influenza vaccination, all reports of serious adverse events following vaccination will need to be closely investigated to confirm or exclude a causal relationship with the vaccine. This is done by the Therapeutic Goods Administration (TGA) with the assistance of expert advisory panels as required.

Adverse Event Reporting: General Public

Vaccine recipients or their family members who wish to report an adverse event following receipt of a pandemic vaccine may do so through the pandemic hotline.

PANDEMIC HOTLINE: 180 2007

Adverse Event Reporting: Immunisation Providers

Any adverse event that the immunisation provider considers to be serious or unexpected should be reported. Immunisation providers and other health care workers should report any serious or unexpected adverse event following H1N1 vaccination just as they would report similar events associated with any other vaccine.

In most States and Territories there is a requirement that serious or unexpected adverse events following immunisation be notified to the relevant health authority in

that jurisdiction. In Tasmania, it is requested that reports be made directly to the Therapeutic Goods Administration (TGA).

For the pandemic (H1N1) vaccination program, immunisation providers may report suspected adverse events following vaccination in their usual way or may elect to report directly to TGA. Information provided to TGA will be shared with relevant State or Territory health authorities for any necessary follow up to be undertaken as required.

It is recommended that reporting to TGA be completed on-line at the following website: <http://www.tga.gov.au/>

Paper-based reports can also be done by completing and submitting a "Blue Card" form which is available for printing from the TGA at the following website: <http://www.tga.gov.au/adr/bluecard.htm>