

## **Principles and Objectives of the National Adverse Event Following Immunisation Surveillance System**

### **Context**

The National Adverse Event Following Immunisation Surveillance System is the national system for passive adverse events reporting and monitoring for all vaccines registered and used in Australia and is just one component of a national framework to ensure vaccine safety.

The safety profile of vaccines is initially determined through clinical trials which are evaluated by the Therapeutic Goods Administration (TGA) prior to the decision to approve the vaccine for use in Australia. Trials are generally undertaken in selected populations and, even when extensive, may not be able to identify rare adverse effects of the vaccine. Post-market monitoring of vaccines is undertaken to identify any change in the safety profile of the vaccine and ensure the continuing safety of the vaccine when in use.

Post-licensure/marketing monitoring encompasses a number of activities which aim to detect, assess, understand and prevent adverse events or any other vaccine-related problem. These activities include those that sponsors are required to undertake as part of their Risk Management Plan (RMP) for the vaccine. Other activities include the analysis of reports of adverse events and the monitoring of literature reports and studies, and in some instances specific active surveillance.

A national adverse event reporting database is maintained by the TGA. Reports are received from many sources including manufacturers, health professionals, state and territory health authorities and consumers. Close liaison between the TGA, the National Immunisation Program (NIP) and state and territory health authorities is required to ensure the effective operation of this database.

The National AEFI Surveillance System is a passive system which may be supplemented by enhanced passive surveillance, sentinel surveillance, active surveillance or post-marketing studies in certain circumstances e.g. the introduction of a new vaccine into the NIP or for the purposes of investigating a possible safety signal.

The National AEFI Surveillance System is designed to detect possible safety signals which require further investigation. The identification and investigation of safety signals is a collaborative process. When determining the appropriate response to a potential vaccine safety signal, safety will be assessed by weighing the net benefit of vaccination as well against the risks.

## **Principles of the National Adverse Event Following Immunisation Surveillance System.**

The National AEFI Surveillance System will operate to:

1. Maintain confidence in the safety of immunisation through the implementation of a robust system of surveillance, reporting, investigation and communication.
2. Minimise the risk of harm from immunisation through the detection of AEFIs and program errors.
3. Inform immunisation policy and practice through a consideration of vaccination risks and benefits.
4. Ensure enhanced surveillance is in place when a new program is implemented.
5. Ensure effective governance, decision making action and communication in response to identified safety signals.
6. Ensure that the reporting processes for vaccine safety surveillance are transparent, public and not affected by conflict of interest.

## **Objectives of the National Adverse Event Following Immunisation Surveillance System**

The operation of the National AEFI Surveillance System will aim to ensure community and health-care provider confidence in vaccine safety by delivering the following outcomes:

1. Monitor and compare reported adverse events or reactions with those that are expected for specific vaccines to assess if AEFIs are occurring within expected rates and level of severity.
2. Identify AEFIs not previously reported.
3. Identify and respond to common programmatic oversights or changes in the AEFI profile of different vaccine lots or brands.
4. Identify and respond to safety signals which may require further clinical and/or epidemiologic investigation, a programmatic response or community/health provider education.
5. Proactively enhance general or targeted surveillance when a new immunisation program is implemented to provide:
  - comparison with previously reported adverse event data; and
  - early validation of potential signals raised in trials or other settings.
6. Analyse and report on adverse events and any safety investigations and make such information regularly available in the public domain.

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## **2 SUMMARY OF OUTCOMES OF RECOMMENDATIONS, APPENDIX 1**

Review of the management of adverse effects associated with Panvax and Fluvax  
(Horvath Review)

7. Provide timely information that can be made available to potential recipients as well as health care providers and the community to help inform the risks and benefits of immunisation.

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