Vaccine Side Effects Under the Microscope

The Gillard Government today released an independent assessment of Australia's management of vaccine adverse events which recommends a more cohesive and coordinated national plan to deal quickly and effectively with health concerns about vaccines.

The Parliamentary Secretary for Health and Ageing, Catherine King, commissioned the review by former Chief Medical Officer, Professor John Horvath AO.

The review followed public alarm over the withdrawal of seasonal flu vaccines for children in the 2010 flu season due to an unusually high incidence of fever with convulsions following vaccination in some children under five years of age.

"The review found that once the first batch of adverse case reports had been received by the TGA its regulatory actions were appropriate and timely," Ms King said.

"The decision by the Chief Medical Officer to suspend use of all seasonal influenza vaccines for children was also considered by the review as appropriate and proportionate to the risk.

"However, the review identified that the arrangements for vaccine safety issues are complex and, while the Therapeutic Goods Administration (TGA) has the key responsibility in monitoring adverse events, many other organisations, including Commonwealth and state health authorities and a number of expert committees, also have a role," Ms King said.

"The 2010 flu vaccine health alert highlighted a lack of clarity of the relationships between these groups and their roles and responsibilities in vaccine safety monitoring and responding to the identification of a possible safety signal."

Ms King said the review notes that there are no Standard Operating Procedures for responding to a vaccine safety issue that does not require regulatory action, but which has possible implications for the use of vaccines in large groups of people such as occurs in the National Immunisation Program.

"The report calls for the an improved system of governance for vaccine safety monitoring and provides a number of options for consideration including the establishment of a Vaccine Safety Committee with broad membership of experts with knowledge of vaccines, vaccine safety, and vaccine program implementation, to
assist the TGA to more effectively implement its vaccine safety responsibilities,” Ms King said.

Other recommendations cover surveillance objectives and actions, the need for timely reporting of adverse events following immunisation, raising community and health professional awareness about vaccine safety monitoring and more transparency by the TGA to ensure better access to vaccine safety information for consumers and health professionals.

"The Government has accepted the thrust of all of the recommendations of the Horvath Review and I have asked the Department of Health and Ageing to form a Working Party to explore ways of implementing reforms," Ms King said.

"Australia has an excellent record of achievement in immunisation against vaccine preventable diseases with high levels of coverage, especially of infants and children.

"Adverse events episodes like the 2010 seasonal flu health alert have the potential to erode public confidence in vaccines and the government is committed to improving governance arrangements to ensure the public has faith in our National Immunisation Program," Ms King said.


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