



## TGA Green Lights Pandemic Flu Vaccine

18 September 2009

Australia's independent medicines' regulator, the Therapeutic Goods Administration (TGA), today announced it will register the CSL pandemic influenza (swine flu) vaccine. This decision paves the way for a national vaccination program to start later this month.

The TGA has been progressively assessing data from adult human trials of the vaccine as they have been provided by CSL and, following an exhaustive evaluation, including consideration by the independent Australian Drug Evaluation Committee (ADEC), the TGA has determined that the vaccine is safe and effective for use in adults.

The human adult trials have indicated that the pandemic vaccine is similar to that of seasonal influenza vaccine with a high safety and low adverse events profile, and that only one injection is required for adults.

The TGA is awaiting further data on the CSL trials of the vaccine for children 9 and under and has therefore not yet made a decision on use of the vaccine in children. This is expected in the near future.

The registration announcement marks the commencement of the vaccination program for adults.

The initial rollout of the vaccine will concentrate on vaccinating front-line health workers and vulnerable people who may experience severe effects from the pandemic influenza. The wider population will also be able to access the vaccine.

State and Territory governments have been developing plans for the delivery of a vaccination program to their populations and the Australian Health Protection Committee (AHPC) has recommended that this begin from 30 September.

The Rudd government has purchased 21 million doses of the vaccine. More than four million doses of the vaccine are already in CSL warehouses in major cities and next week state health authorities will begin delivery to immunisation providers including hospitals and GPs.

The priority groups for the vaccination are:

- Front line health care and community care workers who have direct contact with patients
- People with underlying chronic medical conditions such as asthma, cancers, HIV, heart disease, diabetes, and chronic kidney failure.
- People who are obese with a BMI over 35
- Indigenous people and remote and isolated communities with indigenous people
- Children in special schools, initially only 10 years and over until child safety data is available
- Pregnant women
- Parents and guardians of children aged 0-6 months

The vaccine will be presented in multi- dose vials. This is consistent with countries around the world also seeking to deliver mass vaccination programs. Guidelines for the safe use of the vials have been developed by Australia's specialist immunisation reference group, the Australian Technical Advisory Group on Immunisation (ATAGI) in consultation with the Royal Australasian College of General Practitioners (RACGP) and the Australian Nursing federation (ANF).

The issue around indemnity provision for providers has also been resolved with all indemnity providers confirming they will continue to provide cover.

The Australian Government is committed to ensuring Australia is combating this new strain of influenza in the most effective way possible.

As a vaccine remains our best defence against the pandemic flu, the TGA's decision to approve the vaccine is most welcome.

While the virus has been mild in most people it has had severe effects in some, including more than 100 children. In Australia alone the pandemic flu has been associated with thousands of hospitalisations and 172 deaths. Worldwide there have been more than 3500 deaths associated with this flu strain.

As there is enough vaccine for all adults, I encourage people to protect themselves and their families against the pandemic flu by getting vaccinated.

Information will be available in the coming week from the States and Territories as to where and how people can access the vaccination.

The public can get more information by phoning the Pandemic Flu hotline on 1802007 or visiting [www.healthemergency.gov.au](http://www.healthemergency.gov.au)

**For all media enquires contact the Ministers office: 02 6277 7220**