

## Fact Sheet:

### Alternative BCG Vaccine – Serum Institute of India (BCG-SII)

#### Key points

- The BCG vaccine registered for use in Australia is not currently available
- An alternative vaccine, *BCG SII* may be required to be used under special arrangements
- Patients or their parents/guardians should understand the information provided before consenting to the use of this alternative BCG vaccine

Bacillus Calmette-Guérin (BCG) vaccine is in chronic shortage world-wide and the BCG product registered in Australia is no longer available. Due to this unavailability, the Therapeutic Goods Administration (TGA) has approved the importation of substitute BCG products that are not on the Australian Register of Therapeutic Goods (unregistered products).

This fact sheet provides information on the alternative BCG vaccine (BCG SII) which is being used in some New South Wales TB clinics under the TGA Special Access Scheme (SAS).

#### Why is an unregistered BCG vaccine being used?

To ensure uninterrupted BCG vaccination services in NSW, an alternative BCG vaccine, produced by the Serum Institute of India (SII), may be offered under special prescribing arrangements to people who require BCG vaccine.

#### Is the product safe for me or my child?

A review by the Australian Technical Advisory Group for Immunisation (ATAGI), Australia's peak advisory group that assesses the information available for vaccines and provides advice to government and immunisation service providers found that the BCG SII vaccine is suitable for use and is likely to provide a similar level of protection against tuberculosis (TB) as other BCG products.

The BCG SII vaccine is classified by the World Health Organization (WHO) as 'prequalified'. ATAGI considers this classification provides a considerable level of confidence regarding vaccine safety, due to the assessment processes involved. These processes include independent laboratory testing, WHO site audits of manufacturing facilities and ongoing monitoring of quality product output.

The BCG SII vaccine appears to have a similar safety profile to the vaccine previously available in Australia (Sanofi Pasteur vaccine) based on the limited data available. The available evidence indicates that the rate of side effects should be no greater than that associated with other BCG products.

However, as is the case for other products supplied under these special prescribing arrangements, the TGA advises that they will not accept liability for safety, quality or efficacy of this vaccine.

#### Further information

For further information see the NSW Health BCG Vaccination: Information for Parents available on the NSW TB Program website at [www.health.nsw.gov.au/Infectious/tuberculosis](http://www.health.nsw.gov.au/Infectious/tuberculosis). If you have any further questions you can discuss these with your vaccine provider.