

Chief Health Officer Alert

18 April 2011

Status: Active

Pneumovax23 vaccine second dose suspended

The Therapeutic Goods Administration (TGA) is advising health professionals not to readminister a second dose of Pneumovax23 vaccine.

This is pending the outcome of a review of an increased rate of injection site reactions following administration of the second dose.

Pneumovax23 vaccine is used to prevent life threatening bacterial infections. It has been funded in Victoria since 1998 and was included in the National Immunisation Program in 2005. It is recommended for:

- All people age 65 or over,
- Aboriginal and Torres Strait Islander people age 50 and over,
- Tobacco smokers,
- People age 10 and over who are predisposed to invasive pneumococcal disease.

The Immunisation Handbook currently recommends revaccination 5 years after the first dose.

Pneumovax23 vaccine is known to be associated with a high rate of local injection site reactions. There is varying evidence from published trials as to whether injection site reactions are more common following revaccination.

In March 2011, seven patients vaccinated in New South Wales were reported to have severe local site reactions including cellulitis and abscess. Since notification of this cluster, TGA has worked with the States and Territories to determine whether this event is confined to a specific vaccine batch and has collated and analysed adverse event reports from all States and Territories.

The Australian Technical Advisory Group on Immunisation (ATAGI) is currently reviewing the

place of Pneumovax23 in the National Immunisation Program.

This alert is not applicable to use of the 7-valent pneumococcal conjugate vaccine Prevenar given to children.

Recommendations

Health practitioners are advised not to readminister Pneumovax23 vaccine to patients who have previously received a dose of Pneumovax23 until a review of this matter by the TGA and ATAGI is completed.

Please report all adverse events to Pneumovax23 vaccine to SAEFVIC on 1300 882 924 or at www.saeivic.org.au

Consumers are advised not to seek revaccination with Pneumovax23 if they have previously received this vaccine, until further advice is provided by the TGA and ATAGI.

Any consumer who believes they may have suffered an adverse reaction to Pneumovax23 vaccine is advised to see their health practitioner.

More information

For more information go to: <http://www.tga.gov.au/alerts/medicines/pneumovax.htm> or contact the Immunisation section at the Department of Health on 1300 882 008.



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