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21 June 2022

**RE: Discontinuation of BCG VACCINE injection and alternative supply arrangement under Section 19A of the Therapeutic Goods Act.**

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the discontinuation of the Australian registered **BCG VACCINE *Mycobacterium bovis* (Bacillus Calmette and Guerin (BCG) strain) – AUST R 53569,** LINK has arranged the supply of an alternative product. LINK can supply **BCG Vaccine AJV - Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331 (AJ Vaccines) with Diluted Sauton AJV**, registered and marketed in New Zealand.

**BCG Vaccine AJV - Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331 (AJ Vaccines) with Diluted Sauton AJV** is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **30 June 2024.**

**INDICATION:**
**BCG Vaccine AJV - Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331 (AJ Vaccines) with Diluted Sauton AJV** is recommended for active immunisation in high-risk groups and is to be used as per Australian national immunisation guidelines.

**CONTRAINDICATIONS:**
In Australia, BCG is contraindicated in patients with an allergy to any component of the vaccine or an allergic reaction to a previous does of BCG vaccine; individuals who have previously had tuberculosis or who have a positive tuberculin reaction of over 5 mm; Individuals with significant fever; Individuals with generalised skin disease such as eczema, furunculosis, atopic dermatitis or other exudative or inflammatory dermatologic conditions; patients predisposed to keloid and lupoid reactions, this may occur at the site of injection; individuals with known natural or acquired immunodeficiency conditions or those receiving immunosuppressant therapy; individuals with a high risk of HIV infection where HIV antibody status is unknown.

In addition to the contraindications of the Australian registered product, the following are contraindicated in the use of **BCG Vaccine AJV - Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331 (AJ Vaccines) with Diluted Sauton AJV** Vaccinations should not be administered to:

- Persons in treatment with systemic corticosteroids and other immunosuppressants including radiotherapy. This includes infants exposed to immunosuppressive treatment in utero or via breastfeeding, for as long as a postnatal influence of the immune status of the infant remains possible (e.g. maternal treatment with TNF-α antagonists).
- Persons suffering from malignant conditions (e.g. lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system), those with primary or secondary immunodeficiencies, those with HIV-infection, including infants born to HIV-positive mothers.

- BCG Vaccine SSI should not be given to patients who are receiving anti-tuberculosis drugs.

Vaccinations should be postponed in the case of:

- Persons whose immune status is in question, the BCG vaccination should be postponed until the immune status has been evaluated. The effect of BCG vaccination may be exaggerated in immunosuppressed patients, and a generalised BCG-infection is possible.

**BCG Vaccine AJV - Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331 (AJ Vaccines) with Diluted Sauton AJV** is packaged in the English language and includes an English language package insert. Please contact Link Healthcare Medical Information for a copy of the New Zealand Data Sheet (prescribing information).

The discontinued Australian product and New Zealand product are derived from different substrains of *Mycobacterium bovis* BCG. Therefore, the recommended therapeutic dose and potency are not equivalent. Please refer to the table below for a comparison of the discontinued Australian product and the New Zealand product supplied under Section 19A:

| **Australian BCG Vaccine – Sanofi Aventis** | **New Zealand BCG Vaccine AJV (s19A product)** |
|---|---|
| Vial contains 1.5 mg of live BCG vaccine (attenuated strain of *Mycobacterium bovis* BCG) | Vial contains 0.75 mg live BCG vaccine (*Mycobacterium bovis* BCG, Danish strain 1331) |
| Reconstitute with 1.5 mL of diluent | Reconstitute with 1.0 mL of **Diluted Sauton AJV** (this is supplied with BCG Vaccine AJV) |
| Solution is 1.0 mg/mL (potency is 8 million to 32 million CFU/mL ) | Solution is 0.75 mg/mL (potency is 2 million to 8 million CFU/mL) |
| Dose for an newborns and infants up to 12 months of age is 0.05 mL (potency is 400,000 to 1,600,000 CFU/dose) | Dose for an infant under 12 months of age is 0.05 mL (potency 100,000 to 400,000 CFU/dose) |
| Dose for a child over 12 months and adults is 0.1 mL (potency is 800,000 to 3,200,000 CFU/dose) | Dose for adults and children aged 12 months and over is 0.1 mL (potency 200,000 to 800,000 CFU/dose). |

Reactogenicity

The reactogenicity of the BCG vaccine is influenced by the BCG strain, age at administration, immune status and revaccination. The Danish strain 1331 in the Section 19A **BCG Vaccine AJV** product is known to be significantly more locally reactogenic than the Polish BCG vaccine strain (Brazil Moreau) which has been supplied under Section 19A in Australia. Careful vaccine administration technique as per the vaccine instruction leaflet is recommended.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **BCG Vaccine SSI - BCG Vaccine AJV - Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331 (AJ Vaccines) with Diluted Sauton AJV** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details
Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered BCG vaccine injection.

Yours sincerely,

C Griffin

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