

1 July 2014

Dear Healthcare Professional,

## **Supply of an unapproved Medicine under section 29 of the Medicines Act Bacillus Calmette-Guerin (BCG) vaccine**

### **Background**

Bacillus Calmette-Guerin (BCG) vaccine has been in short supply in NZ and around the world. bioCSL has managed to secure limited supplies of this vaccine which are expected to be delivered in early July. This vaccine was granted consent for distribution in September 1996 in NZ. However, we have been unable to update the registration in time for supply of the first batch for New Zealand.

There are 4 variations to the original 1996 dossier that have not been granted consent. They are:

- The opacity limit in the Finished Product Release Specification has changed
- The shelf life for diluted Sauton (the diluent) has increased from 24 to 36 months
- The Sauton media is now manufactured using water for injection
- A new working seed lot was implemented in 2007

BCG vaccine will therefore be supplied to Healthcare Professionals under Section 29 of the Medicines Act. Section 29 of the Medicines Act deals with the supply of unapproved medicines to Healthcare Professionals for the treatment of a named patient under their care.

bioCSL is advising healthcare practitioners now, so that you will be able to understand the supply requirements for BCG vaccine prior to their need for it.

### **Prescribing Restrictions**

To ensure that the requirements of section 29 are met, Healthcare Professionals will be required to supply the following information to bioCSL:

- the name of the medical practitioner who requested the supply of the medicine
- the name(s) of the patient(s) the medicine was required for
- the name and address of the practice who requested the supply of the medicine

For up to date Bacillus Calmette-Guerin (BCG) vaccine prescribing information, please refer to the Data Sheet available at:

<http://www.medsafe.govt.nz/profs/datasheet/b/BCGCSLinj.pdf>

We estimate these prescribing restrictions will be in place for approximately 6 months. We will inform you as soon as the BCG vaccine registration dossier has been updated and the limitations of Section 29 supply are no longer required.

Yours sincerely

A handwritten signature in black ink, appearing to read "P. Gargiulo".

Pasquale Gargiulo

**Commercial Development & Scientific Affairs Manager**

**bioCSL (NZ) Ltd**