

29 June 2017

Dear Healthcare Professional,

### Supply of Bacillus Calmette-Guerin (BCG) vaccine

As you are well aware, supply of Bacillus Calmette-Guerin (BCG) vaccine has been constrained since mid-2016. With no BCG vaccine being manufactured at our partners Danish manufacturing plant; we are now at a point where there has been no vaccine available in NZ for more than 12 months.

### Future Supplies

A definite resupply date for BCG vaccine is still unavailable.

The manufacturer of BCG vaccine, AJ Vaccines of Denmark (AJV), has been gearing up to restart production. AJV was formally known as Statens Serum Institut (SSI). Please refer to the following link for more information <http://www.ajvaccines.com/news/>.

AJV is currently performing media fill testing with a final report due back in early August. If these are successful, production of BCG vaccine will commence. The first three production batches manufactured will undergo intense validation and quality testing. The accumulated documents from these three batches will be provided to the Danish Regulatory Authority for review. The first batch of BCG vaccine is expected to be released in December.

It is my hope that you will understand that AJV will be releasing the first batches of BCG vaccine to countries where the need is greatest. Thus, New Zealand can expect to receive our first delivery in February. We are continuing to work with the Ministry of Health, PHARMAC and Medsafe and will keep you updated as we make progress. Consequently, we will be writing to you again no later than mid-August to provide you with an update on the media fill testing and an expected availability date.

We apologize for the inconvenience caused by the ongoing lack of supply of BCG vaccine. We would like to take this opportunity to thank both the medical officers of health and the DHB BCG services in anticipation of their continued patience.

For up to date Bacillus Calmette-Guerin (BCG) vaccine prescribing information, please refer to the Data Sheet at: <http://www.medsafe.govt.nz/profs/datasheet/b/BCGCSLinj.pdf>

Yours sincerely



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