



## BCG vaccine for the national immunisation programme

### Use of any remaining SSI stock

Deliveries of a UK licensed BCG vaccine from the Statens Serum Institut (SSI) Denmark continue to be delayed due to manufacturing issues and this vaccine is currently unavailable to order through ImmForm.

Locally held remaining stocks of SSI BCG vaccine are likely to be the most recent distributed by PHE (batch 114022A) and have a labelled expiry of 29 February 2016. PHE recommends that batch 114022A continue to be used for up to six months past its labelled expiry date, based on the known stability of the SSI BCG vaccine and on review of additional information provided by the manufacturer. Further information is available here at [web link 1](#). SSI BCG vaccine of batch 114022A should therefore continue to be administered up to 31 August 2016.

### An alternative unlicensed BCG vaccine will be available shortly

PHE has secured an alternative BCG vaccine. This brand of BCG vaccine is supplied by InterVax Ltd, and manufactured by BB-NCIPD Ltd. In the UK it is being supplied as an unlicensed product, which means it does not have a valid marketing authorisation (licence) in the UK. This vaccine is being provided in accordance with medicines legislation that allows an unlicensed medicine to be supplied when a licensed alternative is not available and the Medicines and Healthcare Products Regulatory Agency (MHRA) has not objected to its importation.

InterVax BCG vaccine is supplied to over 100 countries world-wide including the Netherlands, France, Belgium, Norway and Sweden. Although InterVax Ltd and BB-NCIPD Ltd have not applied to licence the product in the UK, it is a WHO prequalified vaccine meaning it can be used around the world for immunisation against TB. It is also licensed in other EU countries. InterVax BCG vaccine can be used for the national BCG immunisation programme until SSI is able to resume deliveries, expected in 2017.

Where doses of SSI BCG vaccine lot 114022A remain, these should continue to be used until the recommended date of 31 August 2016, and in preference to the alternative unlicensed InterVax BCG vaccine.



## BCG vaccine ordering

Initially, a limited volume of InterVax BCG vaccine will be available to order through ImmForm, alongside PHE's remaining stock of SSI BCG vaccine. Please check the ImmForm website for the latest information available.

Due to the large number of doses per pack for the InterVax BCG vaccine, it is recommended that the vaccine is made available in line with prioritisation advice (below) and to ensure this stock is directed to those at greatest risk. Hence only those accounts likely to see large numbers of high risk infants will initially be given access. ImmForm accounts matching these criteria have been identified and will have access to ordering through ImmForm in the usual manner. Accounts with access will be notified by ImmForm via email shortly, and before the vaccine is made available to order. Ordering will be capped to one pack per account per fortnight and should be ordered according to need and only replaced when more stock is required.

PHE expects to have further InterVax BCG vaccine available later in summer 2016 at which point ordering will be opened to a larger number of ImmForm accounts.

## Description of InterVax BCG vaccine.

Each order of InterVax BCG vaccine through ImmForm will contain the following:

- 1 pack of InterVax BCG vaccine (20 ampoules)
- 1 pack of InterVax BCG vaccine diluent (20 ampoules)
- 10 PHE leaflets for healthcare professionals
- 200 PHE leaflets for patients
- 10 additional plastic squares used to wrap the ampoules prior to opening.



The InterVax BCG vaccine is a different strain of **attenuated Mycobacterium bovis** to the SSI BCG vaccine although it has a **similar efficacy and safety profile**. The presentation of the InterVax BCG vaccine is also different to the SSI BCG vaccine. Each InterVax pack contains twenty 1ml ampoules of freeze dried vaccine which, before use, require careful reconstitution with the separately supplied diluent. This is different to SSI BCG Vaccine which comes as packs of ten 1ml vials.



Each InterVax BCG ampoule contains a maximum of 10, 0.1ml doses (for those aged 12 months and over) or 20, 0.05ml doses (for those aged under 12 months), although the number of doses actually achieved will likely vary in practice.

The manufacturer's information leaflet that comes packaged within each box should be discarded and the PHE leaflets for patients and professionals supplied with each delivery should be referred to instead. Electronic versions of these documents are available at [web link 2](#).

## Administration of InterVax BCG vaccine

Detailed training slides and documents on the reconstitution and administration of the InterVax BCG vaccine are available on PHE's webpages at [web link 2](#).

## BCG prioritisation

During this period of constrained BCG vaccine supply, PHE endorses the World Health Organisation's statement (which can be found at [web link 3](#)), to limit BCG vaccination to neonates and infants of recognised high-risk groups for tuberculosis (TB) or to tuberculin-negative children under five years (groups A-C below). Providers are therefore asked to be responsible in ordering stock for these groups first. Older children who are eligible for the vaccine (groups E-G below), are a lower priority but may be vaccinated alongside younger children to optimise clinic size and avoid any wastage of vaccine.

BCG vaccination for occupational risk reasons (group H below) remain lowest priority and occupational health departments and infection control teams are advised to reinforce their local TB infection control precautions to all staff. Where a health care worker or student is found to be tuberculin negative and is eligible for BCG vaccination, vaccination is not required before that individual is cleared to work as vaccination can be undertaken when further stock becomes available.

## Groups eligible for vaccination

### HIGHEST PRIORITY

**A.** All infants (aged 0 to 12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.<sup>1</sup>

**B.** All infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater.<sup>2</sup>

<sup>1</sup> For country information on prevalence see [web link 6](#).

<sup>2</sup> Universal vaccination operates in areas of the country where the TB incidence is 40/100,000 or greater. This is applied for operational reasons since these geographical areas generally have a high concentration of families who come from regions of the world where the TB incidence is 40/100,000 or greater. The decision to introduce universal vaccination in an area is based on geography in order to target vaccination to children who may be at increased risk of TB in an effective way. It does not imply that living in areas that have an incidence of TB 40/100,000 or greater puts children at increased risk of TB infection. This is because most infections of children are likely to occur in household settings. Further, there has been [little evidence of TB transmission in schools in the UK and little evidence of sustained transmission](#).



**C.** Previously unvaccinated children aged one to five years with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater. These children should be identified at suitable opportunities, and can normally be vaccinated without tuberculin testing.

## **MODERATE PRIORITY**

**D.** Previously unvaccinated, tuberculin-negative children aged from six to under 16 years of age with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater. These children should be identified at suitable opportunities, tuberculin tested and vaccinated if negative as per the Green Book section on tuberculin testing prior to BCG vaccination, available at [web link 4](#).

**E.** Previously unvaccinated tuberculin-negative individuals under 16 years of age who are contacts of cases of respiratory TB (following NICE recommended contact management advice, available at [web link 5](#)).

**F.** Previously unvaccinated, tuberculin-negative individuals under 16 years of age who were born in or who have lived for a prolonged period (at least three months) in a country with an annual TB incidence of 40/100,000 or greater.

**G.** Previously unvaccinated, tuberculin-negative individuals under 16 years of age who are going to live or work with local people for more than three months in a country where the annual incidence of TB is 40/100,000 or greater.

## **LOWEST PRIORITY**

**H.** Individuals at occupational risk.

In addition PHE recommends a case by case opportunistic approach for infants that were eligible but missed vaccination previously.

## **Use of PGD**

As it is unlicensed, InterVax BCG vaccine cannot lawfully be administered or supplied under a Patient Group Direction (PGD).

InterVax BCG vaccine will therefore need to be individually prescribed by using a Patient Specific Direction (PSD), a prescription or patient medicines administration chart. A PSD is the traditional written instruction, signed by a doctor, dentist, or non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.

## **Recording use of BCG vaccine on the clinical and child health systems**

Where a child has been vaccinated using InterVax BCG vaccine, it should be recorded in their GP and child health records as usual.



As with all vaccines, it is very important to record the batch number and expiry date and to report suspected side effects via the Yellow Card Scheme at [web link 7](#).

## BCG vaccine administration and reducing wastage

Stocks of InterVax BCG vaccine are limited and it is therefore essential that vaccine wastage is avoided to ensure that we are able to offer vaccine to as many eligible children as possible. Providers are encouraged to continue to organise the administration of BCG vaccinations in ways that optimise the use of the multi-dose ampoules, for example by scheduling patients requiring BCG vaccine into the same clinic. Please see the PHE training advice at [web link 2](#) on making the best use of the multidose ampoules and storage following reconstitution.

We expect the number of doses extracted from a reconstituted ampoule to vary in practice, depending on the specific type of syringe and needle used, as well as on the surplus of vaccine removed during vaccination. Adherence to guidance on the administration of BCG vaccine, including syringe and needle type, can maximise the number of doses obtained from each ampoule. Please see [web link 4](#) for more information.

## Web links

web link 1	<a href="https://www.gov.uk/government/publications/bcg-vaccine-expiry-extension-for-ssi-bcg-vaccine-batch-114022a">https://www.gov.uk/government/publications/bcg-vaccine-expiry-extension-for-ssi-bcg-vaccine-batch-114022a</a>
web link 2	<a href="http://phe.gov.uk">phe.gov.uk</a>
web link 3	<a href="http://www.who.int/immunization/diseases/tuberculosis/BCG-country-prioritization.pdf">http://www.who.int/immunization/diseases/tuberculosis/BCG-country-prioritization.pdf</a>
web link 4	<a href="https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32">https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32</a>
web link 5	<a href="https://www.nice.org.uk/guidance/ng33/resources/tuberculosis-1837390683589">https://www.nice.org.uk/guidance/ng33/resources/tuberculosis-1837390683589</a>
web link 6	<a href="http://www.who.int/tb/country/data/profiles/en/index.html">www.who.int/tb/country/data/profiles/en/index.html</a>
web link 7	<a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a>