



## BCG vaccine ordering temporarily suspended

Due to on-going manufacturing delays at the Statens Serum Institute (SSI) in Denmark, ordering for BCG vaccine through the ImmForm website is temporarily suspended.

PHE retains a small stockpile for distribution in urgent circumstances. Should you have an urgent requirement please contact the ImmForm helpdesk at [helpdesk@immform.org.uk](mailto:helpdesk@immform.org.uk) and provide details of the volume required and the nature of the request which will be reviewed by PHE.

Where stocks are available locally, please see below for advice on prioritisation for using this stock and information on the expiry date of the most recently supplied batch.

PHE continues to work to secure a suitable replacement BCG vaccine as soon as possible; however it is unlikely that any alternative will be available until later in 2016. Updates will be published through Vaccine Update.

## BCG prioritisation

During this period of constrained BCG vaccine supply, PHE endorses the World Health Organisation's statement (see [weblink 1](#)) and the updated guidance below provides advice on prioritisation of remaining BCG vaccine to neonates and infants of recognized high-risk groups for tuberculosis (TB) or to tuberculin-negative children under 6 years of age (groups A-C below). Providers are therefore asked to be responsible in utilising remaining stocks for these groups first. Older children (aged 6 to under 16 years of age) who are eligible for the vaccine (groups D-G below), are a lower priority.

BCG vaccination for occupational health reasons (group H below) remains lowest priority during this period of constrained BCG vaccine supply. However, those at especially high risk of occupational exposure may require special consideration. 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 is not required before that individual is cleared to work. Vaccination can then be undertaken when further stock becomes available, expected later this year.

## 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>

**C.** Previously unvaccinated children aged 1 to 5 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 (please see Green Book section on tuberculin testing prior to BCG vaccination at [weblink 2](#))

**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, see [weblink 3](#)).

**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.

1. For country information on prevalence see [www.who.int/tb/country/data/profiles/en/index.html](http://www.who.int/tb/country/data/profiles/en/index.html).

2. 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.

## Use of batch 114022A beyond labelled expiry (29/02/2016)

The most recent batch of SSI BCG vaccine that was distributed by PHE (batch 114022A) had an expiry date of 29 February 2016. As BCG vaccine supply from SSI continues to be delayed the MHRA agreed that it is acceptable to use batch 114022A 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.

SSI BCG vaccine from batch 114022A which has been ordered via ImmForm should therefore be retained and can be used past the labelled expiry date, outside of the marketing authorisation, until **31 August 2016**. Batch 114022A of SSI BCG vaccine has not been re-labelled and a letter explaining the extension is being sent out with deliveries and should be kept with the BCG vaccine. The letter is available at [weblink 4](#).

Organisations may continue to supply and administer available BCG vaccine by existing mechanisms, including via Patient Group Direction, as they deem appropriate. The administration of SSI BCG vaccine batch 114022A between 29 February 2016 and 31 August 2016 will be outside of the marketing authorisation (off-label) but there is no licensed alternative in the UK. MHRA have advised that a medicine which is for use outside its licenced indications can be included in a PGD. This use should be formally noted by the organisation but there is no requirement to amend existing PGDs for administration of the product.

Due to the delays mentioned above, this batch represents the only suitable UK supply for some months, and therefore BCG vaccine from Batch 114022A should continue to be held and used past February 2016.

## BCG administration and reducing wastage

Providers are encouraged to organise the administration of locally held BCG vaccine in ways that optimise the use of the multi-dose vials, for example by scheduling patients requiring BCG vaccine into the same clinic.

The number of doses extracted from a reconstituted vial in practice varies, depending on the specific type of syringe and needle used, as well as on the surplus of vaccine removed during vaccination. Adherence to guidelines on the administration of BCG vaccine, including syringe and needle type, can maximise the number of doses obtained from each vial. Guidance on administration of the BCG vaccine can be found at [weblink 5](#) and green book chapter [weblink 2](#).

## Web links

- web link 1 <http://www.who.int/immunization/diseases/tuberculosis/BCG-country-prioritization.pdf>
- web link 2 <https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32>
- web link 3 <https://www.nice.org.uk/guidance/ng33/resources/tuberculosis-1837390683589>
- web link 4 <https://www.gov.uk/government/publications/bcg-vaccine-expiry-extension-for-ssi-bcg-vaccine-batch-114022a>
- web link 5 <http://www.ssi.dk/English/Vaccines/BCG%20Vaccine%20Danish%20Strain%201331/Guidelines%20for%20injection%20of%20BCG%20Vaccine%20SSI.aspx>