



Public Health
England

NHS

A guide for parents and carers

Why is my child being offered unlicensed BCG (TB) vaccine?



immunisation

the safest way to protect your child

There is a global shortage of BCG vaccine that has caused breaks in vaccine supply to the national BCG immunisation programme. Our contracted supplier has not been able to supply us with BCG vaccine.

The risk of contracting TB in the UK remains low, however for eligible babies to still be able to receive BCG vaccine; Public Health England has worked with other suppliers and has secured a short-term supply of BCG vaccine.

This vaccine, made by InterVax, has been a WHO approved vaccine for many years and is used extensively across the globe. However the vaccine does not have a license in the UK.

This leaflet explains why a brand of BCG (TB) vaccine without a UK licence is being used and why the vaccine is still recommended for your child.

What is BCG vaccine?

BCG vaccine contains a weakened form of the bacteria (germs) that cause TB. Because it is weakened it doesn't actually cause TB, but it helps your baby develop protection (immunity) against TB if baby comes into contact with it. The BCG vaccination is particularly effective in protecting babies and young children against the more rare and severe types of TB, such as TB meningitis (swelling of the lining of the brain).

What is the difference between a licensed and unlicensed vaccine?

All vaccines used in the UK are authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). While no medicine is completely risk free, a licence indicates that trials of the medicine's safety and effectiveness have been carried out and the benefits of the medicine are believed to outweigh the risks.

Only when all the information about the vaccine has been accepted by the MHRA or EMA will they be given a licence and be produced and promoted by the manufacturers for general use. An unlicensed medicine may be licensed in other countries but not have a current licence in the UK because the manufacturer has not applied for one.

In certain areas of healthcare, for example in childrens' health, many medicines used are unlicensed. So, not having a UK licence does not mean the medicine is unsafe or untested.

Why isn't there a licensed BCG (TB) vaccine to administer to patients?

There is a global shortage of BCG vaccine. In addition, there have been delays in receiving BCG vaccine from the usual supplier in Denmark. Therefore, to protect your child from TB, Public Health England is importing BCG vaccine from InterVax Ltd of Canada.

This vaccine has been used widely around the world for many years, but it has not been used in the UK so it does not have a UK license. This vaccine is the only suitable alternative BCG vaccine currently available.

Is there another BCG vaccine with a UK licence that my child can have?

No, unfortunately there is no other licensed brand of BCG vaccine available to the UK.

Can I pay to have a UK licensed BCG vaccine?

Due to the current national and global shortage of BCG vaccine, it is unlikely that private doctors or clinics will have supplies of UK licensed BCG vaccine.

Will it be long before UK licensed BCG vaccine is available? Should I wait until then for my baby to have it?

Currently we do not know when a licensed vaccine will become available again.

There is a risk in a very small number of unvaccinated babies of developing TB, including severe types such as TB meningitis. BCG is less effective in protecting against adult-type disease in older age groups. This means that the greatest benefit of BCG is for small babies and infants at risk of severe TB.

Waiting for a licensed vaccine will mean eligible babies lack protection against severe forms of TB such as TB meningitis.

InterVax BCG vaccine is being imported to the UK as an unlicensed product to ensure eligible babies can be protected against TB.

Is the InterVax brand of BCG vaccine safe and effective?

The vaccine has been a World Health Organization (WHO) approved vaccine since 1991, meaning it can be used by United Nations organisations for immunisation against TB.

InterVax BCG vaccine is supplied to over 100 countries world-wide including the Netherlands, France, Belgium, Norway and Sweden. In 2015, over 51 million doses were distributed globally. Studies have shown InterVax BCG vaccine to be highly effective and the vaccine has a good safety record.

Who has PHE asked for advice over the importation of unlicensed BCG vaccine?

Before importing BCG vaccine without a UK licence, PHE has taken advice from the Medicines and Healthcare Products Regulatory Agency (MHRA), the National Institute for Biological Standards and Control (NIBSC), the Joint Committee on Vaccination and Immunisation (JCVI) and the Department of Health (DH).

Unlicensed BCG vaccine is being imported into the UK in accordance with medicines legislation, which is permitted when there are shortages of a suitable licensed product. The MHRA has not objected to the importation of the Intervax vaccine.

PHE has also consulted with WHO and other European countries where the vaccine is in use.

How is the InterVax BCG vaccine given?

The vaccine is given in exactly the same way as other brands of UK licensed BCG vaccine by a small injection just under the skin, known as an intradermal injection.

What reaction can be expected after immunisation with InterVax BCG vaccine?

Following immunisation with BCG vaccine a small bump appears at the injection site. This is followed after two or three weeks by a red bump. In some cases a small abscess can occur. This heals without treatment in a few weeks.

Where can I find out more information about InterVax BCG vaccine?

You can speak to your doctor, nurse or midwife about the use of InterVax BCG vaccine. There is also a leaflet available with the vaccine for you to read.

