

23 February 2016

Dear Colleague

BCG vaccine batch 114022A manufactured by Statens Serum Institute

BCG vaccine to protect against tuberculosis used in the United Kingdom is supplied by a single manufacturer (Statens Serum Institute (SSI)) and is procured by Public Health England (PHE) for the UK nations. The manufacturer has experienced supply problems which resulted in a shortage of BCG vaccine in 2015, when for several months no vaccine was available. Some vaccines did become available in September 2015, but the available batch had an expiry date of 29 February 2016. The vaccine manufacturer has now advised PHE they will not be able to supply further vaccine in the near future.

In a letter issued to all organisations holding centrally supplied BCG vaccine, PHE advised that the current stated shelf life of SSI BCG vaccine batch 114022A can be extended by 6 months from 29 February 2016 to **31 August 2016**. The letter from PHE is available at [web-link 1](#).

All vaccines have to be authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) before they can be placed on the market for use in all parts of the UK. This extension to the shelf life was agreed by MHRA. Based on the known stability of the SSI BCG freeze dried vaccine and on review of additional information provided by the manufacturer, MHRA have agreed it would be acceptable to use this batch for up to six months after its expiry date in order to meet the current shortage and therefore to continue to be able to vaccinate to protect high risk infants against TB until PHE can obtain a further supply of BCG vaccine.

In agreeing to extend the shelf life of the vaccine to 31 August 2016 the MHRA are indicating the vaccine will remain effective at providing protection against TB provided the vaccine has been stored appropriately. The use of this vaccine up to 31 August 2016 is supported by a review of stability data by MHRA.

There is no evidence the adverse effect profile in vaccine with the extended shelf life will be different to vaccine used in accordance with the original shelf life.

The administration of SSI BCG vaccine batch 114022A between 01 March 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 licensed 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.

Furthermore the Nursing and Midwifery Council (NMC) standards section 7, standard 22 states *“that medication which is licensed but used outside its licensed indication may be administered under a patient group direction where such use is exceptional, justified by best practice and the status of the product is clearly described.”* The NMC standard is available at [web-link 2](#).

In accordance with NMC standards for proficiency of nurse and midwife prescribers available at [web-link 3](#) when providing information for patients about the license for their medicines it is considered sufficient to explain in general terms why the medicine is being used outside its license. Formal consent for the use beyond its expiry is not required.

As there is a serious global shortage of BCG this batch will be the only suitable supply for patients in Scotland and there is therefore still a need to prioritise use of BCG in line with the advice issued in September 2015 available at [web-link 4](#), but the extension of this shelf life of this batch ensures Scotland is able to ensure the protection of the most vulnerable groups. Please note the extension of expiry date to 31 August 2016 only applies to SSI vaccine batch 114022A.

You may find the Appendix with Questions and Answers, useful for your interaction with patients.



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References

Web-link 1

<https://www.gov.uk/government/publications/bcg-vaccine-expiry-extension-for-ssi-bcg-vaccine-batch-114022a>

Web-link 2

<http://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/>

Web-link 3

<http://www.nmc.org.uk/standards/additional-standards/standards-of-proficiency-for-nurse-and-midwife-prescribers/>

Web-link 4

<http://www.documents.hps.scot.nhs.uk/immunisation/scottish-vaccine-update/issue41-2015-09.pdf>

BCG vaccine: Extension of expiry date

Information for parents

What is tuberculosis (TB)?

TB is an infection which usually affects the lungs but can affect the whole body. It can be dangerous and difficult to treat. Babies and young children are particularly at risk of TB. A vaccine (BCG) is available to help protect against TB.

Your baby/child has been identified as being someone who would benefit from vaccination against TB at an early stage in their life.

Why am I being given this information on the BCG vaccine now?

From 1 March 2016 the BCG vaccine being used in the UK will have an extended expiry date. This is because the company who supplies the BCG vaccine has advised the NHS across the UK that they will not be able to supply any more vaccine for the time being.

Is this only a problem in the UK?

No, there have been world-wide problems with the supply of BCG vaccine. The UK is currently trying to find another source of BCG vaccine.

The World Health Organisation (WHO) has called on all countries to identify individuals who will benefit most from BCG vaccination.

What is the expiry date of a vaccine?

The expiry date is the date the manufacturer guarantees the full strength and safety of the vaccine. The expiry date does not indicate a point when a medication becomes harmful or stops being effective. BCG is a live vaccine which is freeze dried. It is a stable vaccine which remains effective over a long period of time.

Why has the expiry date been extended?

The Medicines and Healthcare products Regulatory Agency (MHRA) is the group in the UK which assess medicines and vaccines before they are put on sale. Part of the assessment process requires the vaccine to have an expiry date.

To ensure that BCG vaccination can continue until a new supply is organised, the MHRA has assessed the available evidence for how stable the BCG vaccine is and have asked for additional information about the vaccine from the company supplying it.

The MHRA have concluded it is acceptable to use the current batch of BCG vaccine until 31 August 2016.

Will the vaccine still be effective?

The MHRA have indicated BCG vaccine will remain effective at providing protection against TB.

Will the vaccine be safe?

There is no evidence any side effects from vaccine past the expiry date will be any different to vaccine used within the expiry date.

I've heard of medicines sometimes being used "unlicensed". Is using the vaccine past the expiry date counted as an unlicensed medicine?

No, it is not an unlicensed medicine. While giving the vaccine will be outside the usual marketing, there is no licensed alternative vaccine available in the UK. In addition, the supply of this vaccine up to 31 August 2016 is supported by Health Protection Scotland and the MHRA, and protecting your family against TB is important.

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