



All organisations holding centrally supplied BCG vaccine

25th January 2016

Dear Colleague,

BCG Vaccine batch 114022A manufactured by Statens Serum Institute (SSI)

In 2015, there was a shortage of centrally supplied BCG vaccine manufactured by the Statens Serum Institute (SSI), with ordering through ImmForm suspended for several months. Ordering reopened in September 2015, but the available batch, 114022A, is relatively short dated to 29 February 2016.

Based on the known stability of the SSI BCG vaccine and on review of additional information provided by the manufacturer, MHRA have agreed that it would be acceptable to use this batch for up to six months after its expiry date in order to meet the current shortage.

The purpose of this letter is therefore to advise you that the current shelf life of SSI BCG vaccine batch 114022A can be extended by 6 months from 29 February 2016 to **31 August 2016**.

Organisations that hold centrally supplied SSI BCG vaccine from batch 114022A should therefore retain and use this batch past the labelled expiry date, outside of the marketing authorisation, until 31 August 2016. Batch 114022A of SSI BCG vaccine will not be re-labelled so you will need to keep this letter with your stock as confirmation of the revised expiry date. As there is a serious global shortage of BCG, this batch may represent the only suitable UK supply for some months, and therefore it must not be discarded after February.

Organisations may continue to supply and administer 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.

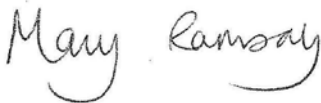
MHRA have advised that a medicine which is for use outside its licenced indications can be included in a PGD. This use should be formally noted by the organisation but there is no requirement to amend existing PGDs for administration of the product.

The supply of this vaccine up to 31 August 2016 is supported by authoritative clinical guidance from PHE and by a review of stability data by the MHRA. Therefore in accordance with GMC guidance¹, 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, but health care professionals must always answer questions from patients (or their parents or carers) about medicines fully and honestly. If required, further information for patients and health care workers on off-license use of vaccines is available on the PHE website².

Please note that the extension of expiry date to 31 August 2016 only applies to SSI BCG vaccine batch 114022A.

If you have any queries about the above, please email vaccinesupply@phe.gov.uk

Yours sincerely



Dr Mary Ramsay, FFPHM
GMC 3065677
Consultant Epidemiologist and Head
Immunisation, Hepatitis & Blood Safety
Department
National Infection Service
Public Health England



Mr Gareth Thomas
Head of Vaccines & Countermeasures
response
National Infection Service
Public Health England

¹ Good practice in prescribing and managing medicines and devices (2013)
http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

² <https://www.gov.uk/government/publications/off-label-vaccine-leaflets>