NHS Pharmacy and medicines management teams

8th August 2016

Dear Colleague,

Re: BCG vaccine shortages and mitigating actions

As you may be aware there is a global shortage of BCG vaccine. In addition, there have been problems with the supply of the only BCG vaccine with a UK marketing authorisation from Serum Statens Institut (SSI) of Denmark. Supplies of this vaccine are currently unavailable and future supplies are not guaranteed. This has led to a shortage of BCG vaccine in the UK and in response PHE have initiated the following actions:

- Prioritisation of available stocks of BCG. Currently eligible new-borns in high BCG usage areas are being prioritised to receive BCG vaccine
- In conjunction with MHRA, agreed an extension to the expiry date of the remaining SSI stock (Batch number 114022A) from February 2016 to August 2016
- Procurement of an interim supply of BCG vaccine from InterVax Ltd of Canada. InterVax BCG vaccine (which is manufactured in Bulgaria) has been a WHO prequalified vaccine for 25 years and has been used extensively across the globe, however this vaccine does not have a current UK marketing authorisation. It has been procured to re-start the neonatal BCG immunisation programme.

Since the InterVax BCG vaccine became available for ordering by provider organisations in high BCG usage areas, PHE have received a number of enquiries from healthcare professionals about its use. These enquiries have mostly been about

- unlicensed use,
- quality of the vaccine,
- international use of the vaccine,
- Patient Group Directions (PGDs) and
- reconstitution and subsequent storage in an opened ampoule.
Public Health England recognises that the unlicensed status of the vaccine, combined with the ampoule presentation requiring reconstitution, especially when combined with the need to continue multi-dose use in order to minimise wastage is unusual. This can present pharmacists, doctors, nurses and other health professionals with some challenges. Despite these concerns it must be remembered that this brand of vaccine is currently the only one available to the UK; there is no alternative UK licensed or unlicensed brand. It is important that health professionals involved in the provision of BCG immunisation services, recognise that this BCG vaccine from InterVax is the only means by which those most at risk of serious forms of TB can be protected.

In order to support healthcare professionals in the use of InterVax BCG vaccine, PHE has developed a suite of materials. In order to be fully informed, all of the documents listed below should be read. The healthcare worker factsheet has been updated to address all the enquiries raised above.

In producing these materials PHE have aimed to be as thorough as possible in anticipating and meeting your needs. However, if you wish to give any constructive feedback or make useful suggestions to improve these materials, please email immunisation@phe.gov.uk

Yours sincerely

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Immunisations

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List of publications for health professionals:
Healthcare professional factsheet and training slides:

Unlicensed BCG vaccine: advice for healthcare professionals:
https://www.gov.uk/government/publications/unlicensed-bcg-vaccine-advice-for-healthcare-professionals

BCG vaccine: use of SSI BCG vaccine batch 114022A post expiry:
https://www.gov.uk/government/publications/bcg-vaccine-expiry-extension-for-ssi-bcg-vaccine-batch-114022a

Special edition of Vaccine Update which includes priority groups for InterVax BCG

InterVax EU Batch Release Certificate and Certificate of Analysis
https://www.gov.uk/government/publications/intervax-bcg-vaccine-certificates

Template letter to communicate with parents whose babies missed BCG immunisation

List of publications for patients and parents

Unlicensed BCG vaccine: guide for parents and carers:

Tuberculosis: the disease, its treatment and prevention