Public Health England

Immunisation and Countermeasures Division
Public Health England, 61 Colindale Avenue
London NW9 5EQ

31 October 2018

Att: Chief pharmacists

Re: Discarding all Intervax Ltd BCG vaccine and diluent product

I am writing to alert you to a BCG vaccine administration error that PHE has been notified of and the actions that need to be taken to prevent this happening going forward.

National BCG programme – vaccine supply
BCG vaccine is centrally supplied by PHE to the NHS in line with national policy to selectively offer vaccination to those at increased risk of exposure to tuberculosis infection. PHE issued a letter in July advising the NHS that supply of the sole UK-licensed BCG vaccine (manufactured by AJ Vaccines) had resumed for use in the national BCG programme. It also advised that this would replace the Intervax Ltd BCG vaccine over time, which had been supplied to enable the continuation of the programme during earlier supply interruption.

PHE re-opened ordering for the UK-licensed AJ Vaccines product in late August 2018. At the time, colleagues in the NHS were asked to use up locally held InterVax BCG vaccine stocks before ordering AJ Vaccines BCG Vaccine in order to minimise vaccine wastage.

BCG vaccine administration error
PHE has been notified of two separate serious untoward incidents involving acute trusts delivering the BCG programme to neonates. In one incident the diluent supplied with the AJ Vaccines product was used to reconstitute the Intervax BCG vaccine and in the other incident the Intervax diluent was used to reconstitute the AJ Vaccines product. Both incidents are currently still under investigation.

The components of the two diluents are different and both the Intervax Ltd SPC and AJ Vaccines SPC are clear that each vaccine should **only** be reconstituted using the accompanying diluent produced by the same manufacturer.

PHE has alerted the MHRA of the two incidents and reports of adverse events will be monitored through the Yellow Card Scheme in the usual way.

Discarding all Intervax Ltd BCG vaccine
PHE has since stopped issuing Intervax Ltd BCG vaccine but we are aware that there may still be packs of locally held vaccine and diluent. In order to reduce the risk of the error identified occurring in the future, PHE is advising that **any remaining locally held stock of the Intervax Ltd BCG vaccine is now disposed of safely.** Only the AJ vaccines BCG product (vaccine and diluent) should be used going forward and this can be ordered through ImmForm in the usual way.

Local Action Required by Chief Pharmacists:

- **ALL** remaining stock of the Intervax Ltd BCG vaccine and diluent should be discarded.
- The unused Intervax Ltd vaccine vials and diluent vials should be safely disposed of according to local protocols and in line with the guidance specified in Chapter 32 of the Green Book on Tuberculosis which states that BCG vaccine waste should be disposed of in accordance with the recommendations for waste classified as potentially cytotoxic / cytostatic (in a purple-lidded container). See chapter for full details.
- Relevant teams to be aware that **only** the **AJ vaccines BCG product** (vaccine and diluent) should be used going forward- all ordering should be done through ImmForm in the usual way.
- PHE have produced this poster as a visual aid to remind all teams of the above. This poster should be displayed clearly in high risk areas where the vaccine is likely to be administered.

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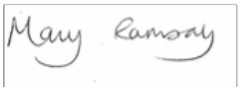
Yours faithfully,



Dr Mary Ramsay

Consultant Epidemiologist and Head