



Briefing Note

Serial number: 2017/033

Date: 25 July 2017

Event: Global hepatitis B vaccine shortage: impact on UK supply and temporary vaccine recommendations in view of supply constraints

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Background and Interpretation

There is a global shortage of monovalent hepatitis B containing vaccines impacting severely on UK supply of monovalent and combined hepatitis A/hepatitis B vaccine. This is due to intermittent manufacturing issues which have resulted in increased demand on all manufacturers' supplies of vaccine. The vaccine shortages are likely to continue for the rest of this year.

In light of these supply issues, Public Health England (PHE) has drafted temporary advice on prioritisation of groups, on alternative vaccine use and on dose sparing options. The aim of the guidance is to preserve adult and paediatric monovalent hepatitis B vaccine stock for those at highest immediate need and with the greatest ability to benefit.

As PHE does not centrally procure or supply monovalent or bivalent hepatitis B vaccines (unlike hepatitis B containing hexavalent vaccine which is procured for the routine childhood programme), PHE does not have a stockpile and has limited control over the distribution of available stock. PHE is working closely with DH and the manufacturers, however, to try to prioritise remaining monovalent hepatitis B stock for the UK and to prevent complete stock-outs for groups at highest immediate risk.

Manufacturers have instituted ordering restrictions to help prioritisation and prevent stock from being rapidly exhausted. Manufacturers have also put in processes to allow exceptional requests for additional doses if there is a clear clinical and/or public health need either for an individual patient or as part of an outbreak response.

Vaccination should not be delayed in infants born to hepatitis B infected mothers - they are the highest priority for post-exposure vaccination as they are at greatest individual risk of infection, having been exposed to a substantial amount of infected blood during the birthing process.



For all other pre and post exposure indications, an individual risk assessment is required. In general, the risk of acquiring infection from an exposure incident with a known infected source is higher than that from an unknown source or in most pre-exposure situations, but clinical judgement is required.

The temporary guidance is available here:

<https://www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints>

It also appears on the main Gov.uk Hepatitis B page under vaccination:

<https://www.gov.uk/government/collections/hepatitis-b-guidance-data-and-analysis>

Many of the alternative vaccine options will be off-label use of licensed products. For further information on off-label use of vaccines see:

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

This temporary guidance does not replace the Green Book or Immunoglobulin handbook recommendations but should be read in conjunction with them.

Vaccine stock situation updates from manufacturers are posted in the monthly Vaccine Update: <https://www.gov.uk/government/collections/vaccine-update>. It should be noted that the situation is very dynamic and may change frequently.

Implications and Recommendations to PHE Centres

HPTs in PHE Centres may receive additional queries regarding availability of vaccines and clinical prioritisation if limited supply. HPTs are advised to refer enquirers to the temporary guidance and share the guidance with local health providers and commissioners, as appropriate.

References/ Sources of information

1. Immunisation against Infections Disease (the Green Book) Department of Health (2006). Hepatitis A Chapter 18
<https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>
2. Immunoglobulin Handbook Hepatitis B
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/327768/Hepatitis_B_immunoglobulin_Oct_2008.pdf
3. The National Travel Health Network and Centre (NaTHNaC)
<http://nathnac.net/#/>