

Temporary shortage in monovalent paediatric hepatitis B vaccine: implications and recommendations

Issue:

We have been informed that GPs have had problems ordering paediatric hepatitis B vaccine this month due to manufacturer supply shortages. On investigation this seems to have stemmed from a stock out at GSK of Engerix-B and limited stock at Sanofi Pasteur MSD for HBvaxPRO Paediatric.

We have been advised by GSK that their stock has been restored this week. SPFMSD have sufficient stock to cover standing orders and are taking back orders for delivery during June, but supply is likely to remain limited until late July. There are no alternative paediatric monovalent hepatitis B vaccine available in England.

Implications:

GPs and other providers may have temporary stock shortages in the coming months. This is of particular concern for infants who should receive timely vaccination in the neonatal selective immunisation programme for infants born to hepatitis B infected mothers since the vaccine is given post high risk exposure.

In the absence of alternative paediatric products, the GSK and SP MSD hepatitis B adult vaccine products (Engerix-B and HBvaxPRO) may need to be used (see doses and volumes in table below). On review of available data on use of adult doses in children, no evidence of additional risk to infants and children was found, noting that limited data exist. However, before the introduction of paediatric hepatitis B vaccines, adult dose vaccine was routinely given as standard to children.

Vaccine product (manufacturer)	Ages	Dose	Volume
Engerix B® (GSK)	0-15 years	10µg	0.5ml
Engerix B® (GSK)	16 years and over	20µg	1.0ml
HBvaxPRO Paediatric® (SPMSD)	0-15 years	5µg	0.5ml
HBvaxPRO® (SPMSD)	16 years or over	10 µg	1.0ml

Source: Green Book: Immunisation against Infectious Disease, Chapter 18: Hepatitis B, table 18.1

Recommendations:

During this period of potential limited stock, if GPs have no paediatric hepatitis B vaccine when it is indicated for a patient, the following is advised:

1. POST EXPOSURE VACCINATION - e.g. SELECTIVE NEONATAL IMMUNISATION PROGRAMME
 - Vaccination of the child should not be delayed
 - The child should be vaccinated with half the volume of the adult dose (i.e. half the volume (0.5ml) in an adult dose pre-filled syringe).
 - If there are no or unclear graduated markings on the adult pre-filled syringe to indicate 0.5ml, the full volume (i.e. an adult dose) should be given to avoid under-dosing the child
 - This will be off-label use of the adult vaccine and PGDs in current use are unlikely to specifically cover this, therefore a PSD will be required
2. PRE EXPOSURE VACCINATION e.g. for travel
 - If limited stock exists, paediatric vaccine should be prioritised for post-exposure vaccination and in particular for the selective neonatal programme
 - An assessment should be made as to whether the risk of exposure is imminent and, if not, whether pre-exposure vaccination can be delayed in that child
 - If vaccination cannot be delayed, use half adult dose as described above

If adult dose(s) of hepatitis B vaccine have been used in a child, the course can be completed with paediatric dose when vaccine available.