

# WELSH HEALTH CIRCULAR



Llywodraeth Cymru  
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**CATEGORY: PUBLIC HEALTH**

**Title: Introduction of the hexavalent ("6 in 1") vaccine including hepatitis B into the routine immunisation schedule for babies born on or after 1 August 2017**

**Date of Expiry / Review N/A**

**For Action by:**

General Practitioners  
Chief Executives, Health Boards  
Chief Executive, Public Health Wales

**For information to:**

Medical Directors, Health Boards  
Nurse Executive Directors, Health Boards  
Directors of Public Health, Health Boards  
Immunisation Leads, Health Boards  
Head VPD Programme, Public Health Wales

**Sender:**

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Dear Colleague,

As notified in WHC 2017/22, in late September/early October, Infanrix hexa® (DTaP/IPV/Hib/HepB) will replace both Pediacel® and Infanrix/IPV+Hib® (DTaP/IPV+Hib) for routine childhood immunisations at 8, 12 and 16 weeks of age for children born on or after 1 August 2017.

The introduction of a hexavalent vaccine means that as well as being protected against diphtheria, tetanus, pertussis, polio and Hib, babies will also be protected against hepatitis B.

The introduction of a vaccine which protects against hepatitis B is an important milestone in the fight against viral hepatitis and meets the World Health Organisation's recommendation that every country should routinely immunise children against hepatitis B as part of the global strategy to eliminate this virus.

### **Routine immunisation schedule**

There is no change to the timing of the routine childhood immunisation schedule with the introduction of the hexavalent vaccine which will provide a direct replacement for current vaccines. Babies born on or after 1 August 2017 will be offered Infanrix hexa® (DTaP/IPV/Hib/HepB) in place of pentavalent vaccine (DTaP/IPV/Hib) at 8, 12 and 16 weeks of age. See Table 1 below.

**Table 1 - The routine childhood immunisation schedule following the introduction of Infanrix hexa®**

<b>Age</b>	<b>Diseases protected against</b>	<b>Vaccines used</b>	
8 weeks	<b>Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B</b>	Infanrix hexa	DTaP/IPV/Hib/HepB (thigh)
	Pneumococcal	Prevenar 13	Pneumococcal conjugate vaccine (PCV) (thigh)
	Meningococcal group B	Bexsero	MenB (left thigh)
	Rotavirus	Rotarix	Rotavirus (oral)
12 weeks	<b>Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B</b>	Infanrix hexa	DTaP/IPV/Hib/HepB (thigh)
	Rotavirus	Rotarix	Rotavirus (oral)
16 weeks	<b>Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B</b>	Infanrix hexa	DTaP/IPV/Hib/HepB (thigh)
	Pneumococcal	Prevenar 13	Pneumococcal conjugate vaccine (PCV) (thigh)
	Meningococcal group B	Bexsero	MenB (left thigh)

## Changes to the selective immunisation schedule

The schedule has changed for the selective neonatal hepatitis B immunisation programme for babies born to hepatitis B infected mothers. See Table 2 below. These babies will still require a dose of monovalent vaccine immediately after birth and at 4 weeks of age and will then follow the routine schedule with hexavalent vaccine at 8, 12 and 16 weeks of age. They will require a further dose of monovalent hepatitis B vaccine at 12–13 months of age and should be tested to exclude infection at the same time (see table 2 below). A further dose of hepatitis B-containing vaccine at 3 years and 4 months is no longer recommended for those children who have completed their routine primary immunisations with the hexavalent hepatitis B-containing vaccine.

However, the pre-school booster visit (for MMR and DTaP/IPV or dTaP/IPV vaccinations) provides an opportunity to check the child has been appropriately managed, i.e. fully immunised against hepatitis B and tested for infection.

**Table 2 - Hepatitis B in the immunisation schedule for routine childhood and selective neonatal hepatitis B programmes following the introduction of the Infanrix hexa®**

Age	Routine Childhood	Babies born to hepatitis B infected mothers
Birth		<b>Monovalent HepB (Engerix B or HBvaxPRO Paediatric)</b> (with HBIG if indicated)
4 weeks		<b>Monovalent HepB (Engerix B or HBvaxPRO Paediatric)</b>
8 weeks	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)
12 weeks	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)
16 weeks	DTaP/IPV/Hib/HepB (Infanrix hexa)	DTaP/IPV/Hib/HepB (Infanrix hexa)
12 – 13 months		<b>Monovalent HepB (Engerix B or HBvaxPRO Paediatric)</b> <b>Test for HBsAg</b>

## Presentation of hexavalent vaccine

Infanrix hexa® is presented as a pre-filled syringe and a separate vial containing the powdered Hib component. The vaccine must be reconstituted by adding the contents of the pre-filled syringe to the vial containing the powder. Further details can be found in the Infanrix hexa® Summary of Product Characteristics at:

<https://www.medicines.org.uk/emc/medicine/33313>

## **Vaccine ordering and minimising wastage**

Infanrix hexa® is expected to be made available to order through ImmForm from the beginning of September 2017 in readiness for the planned switch over in late September/early October 2017.

To avoid potential wastage, ImmForm customers should aim to run down the volume of DTaP/IPV/Hib (PediaceL® and Infanrix-IPV+Hib®) vaccines held in stock and only order the minimum volume to complete vaccination of babies born before 1 August 2017.

Infanrix hexa® should only be given to older babies (i.e. born before 1 August 2017) if there are no locally held pentavalent vaccine stocks and no further PediaceL® or Infanrix-IPV+Hib® can be ordered through ImmForm. Vaccination should never be delayed in order to obtain the pentavalent vaccine.

Following the introduction of Infanrix hexa® for babies born on or after 1 August 2017, in order to avoid any wastage of the existing vaccines used for this programme, any remaining stocks of DTaP/IPV/Hib (PediaceL® and Infanrix-IPV+Hib®) should be used for babies who have already started courses with PediaceL® or Infanrix-IPV+Hib® (second or third dose). If vaccine supplies still remain, then as a temporary measure, DTaP/IPV/Hib (PediaceL® or Infanrix-IPV+Hib®) can be used for pre-school boosting at the age of 3 years and 4 months.

Once DTaP/IPV/Hib stocks are used up, pre-school boosting should revert back to Repevax® (dTaP/IPV) or Infanrix IPV (DTaP/IPV).

## **'Immunisation against infectious disease' (the Green Book)**

The hepatitis B chapter of the Green Book has been updated and is available at:

<https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>

## **Patient Group Directions**

Patient group direction (PGD) templates have been made available from <http://nww.immunisation.wales.nhs.uk/pgds-psds> to support the introduction of DTaP/IPV/Hib/HepB into the routine childhood immunisation programme: a PGD template for the administration of DTaP/IPV/Hib/HepB and a DTaP/IPV/Hib Booster PGD template.

The DTaP/IPV/Hib Booster PGD template has been developed to facilitate the use of remaining supplies of DTaP/IPV/Hib (PediaceL® or Infanrix/IPV+Hib®) vaccine, for the pre-school booster, from 3 years and 4 months of age. Such use is recommended to prevent vaccine wastage, should supplies of DTaP/IPV/Hib remain following the introduction of DTaP/IPV/Hib/HepB into the routine childhood immunisation programme.

The existing DTaP/IPV/Hib PGD template remains available to allow for the continued primary immunisation of infants born before 1 August 2017 with DTaP/IPV/Hib, so long as supplies remain available.

## **Recording immunisations given**

NHS Wales Informatics Service have updated the Child Health systems to allow for call and recall of infants for this new vaccine. Healthcare professionals administering the vaccine must ensure that information on vaccines administered is documented in the general practice record and parent held record. The healthcare professional must ensure that information on vaccines administered is submitted directly to the Health Board Child Health Office within 7 days.

Arrangements continue to be required to inform neighbouring areas when children resident in their area are immunised outside their local area through the child health system.

Data to monitor vaccine uptake will be collected through the Child Health System in the same way that data for existing childhood immunisation programmes are collected. Immunisation uptake will be reported through the Public Health Wales COVER scheme.

For accurate monitoring of immunisation uptake, it is essential that completed lists for scheduled vaccination sessions are returned to Health Board Child Health Offices in a timely manner. It is also essential that any unscheduled Infanrix hexa® vaccines given opportunistically are reported to Health Board Child Health Offices using an unscheduled form. Timely return of immunisation forms from General Practice is not only important for immunisation uptake monitoring, but also because late return of forms may have consequences for the Child Health System in appointing children for future immunisations.

## **The Red Book – Personal Child Health Record (PCHR)**

The Red Book includes an 'additional vaccine page' where Hepatitis B given to infants at increased risk can be recorded.

Other pages of the Red Book will be updated to reflect the introduction of the hexavalent vaccine at the next reprint.

## **Funding and service arrangements**

There will be no changes to the funding arrangements for this programme following the change in vaccine.

The Directions to Local Health Boards as to the Statement of Financial Entitlements Directions 2013 will be amended in due course to reflect the change to the vaccine.

## **Publicity and Information Materials**

A new '6 in 1' leaflet is available on the NHS Direct (Wales) web site via the link below.

<http://www.nhsdirect.wales.nhs.uk/livewell/vaccinations/Leaflets/>

Hard copies of leaflets will be available to order in due course by emailing:

[hplibrary@wales.nhs.uk](mailto:hplibrary@wales.nhs.uk)

or telephoning 029 2010 4650

The following are also available to download from NHS Direct (Wales) via the weblink :

- 'Is your child up to date with their immunisations?' poster
- Routine Childhood Immunisation Schedule for Wales from October 2017

Further information for healthcare professionals including 'Question and Answer' sheets and a training slide set are available from the Vaccine Preventable Disease Programme, Public Health Wales, NHS Wales intranet site at:

<http://nww.immunisation.wales.nhs.uk/hepatitis-b-childhood-immunisation-progr>

Thank you for your support in delivering this important programme.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'I. Rees', written in a cursive style.

**IRFON REES**

Deputy Director, Public Health Division