# The hexavalent DTaP/IPV/Hib/HepB (6 in 1) combination vaccine

Information for healthcare professionals about the inclusion of hepatitis B vaccine in the **routine** infant immunisation programme

#### Background

Since autumn 2017, all babies have been eligible for a hexavalent vaccine which includes hepatitis B (HepB) for their primary immunisations. This vaccine, called Infanrix hexa® (and Vaxelis® if available), replaced the pentavalent infant vaccines Infanrix®-IPV+Hib and Pediacel®.

The following questions and answers are intended to provide healthcare professionals with more information about this vaccine.

#### What are the hexavalent vaccines?

Infanrix hexa® and Vaxelis® are combination vaccines used for primary vaccination of infants to protect against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and disease caused by *Haemophilus influenzae* type b. These hexavalent vaccines can also be used for catch-up immunisation for children up to their 10th birthday, where these children have missed out on doses of primary immunisations. Multiple studies have shown Infanrix hexa® and Vaxelis® to be safe and highly immunogenic for all its component toxoids/antigens.

#### Interchangeability of Infanrix hexa® and Vaxelis®

Vaxelis® and Infanrix hexa® vaccines are considered interchangeable, but where possible and if local stock allows, it is preferable that the same DTaP/IPV/Hib/HepB vaccine be used for all 3 doses of the primary course. However, vaccination should never be delayed because the vaccine used for previous doses is not known or unavailable.

The hexavalent vaccine brand available in Northern Ireland will be dependent on product availability as guided by HSC Trust Pharmacy/The Regional Pharmaceutical Procurement Service (RPhPS).

#### When was the hexavalent vaccine introduced into the infant schedule?

All babies born are eligible for the vaccine eight weeks after their birth. Hexavalent vaccine is

available to order for use in the routine childhood primary immunisation schedule at 8, 12 and 16 weeks of age.

From 1 July 2025, a 4th dose of the hexavalent vaccine has been introduced into the UK schedule (replacing the previous 12 month dose of Hib/MenC). This is to be given at 18 months of age to children with a date of birth on or after 1 July 2024, to boost protection against Hib.

#### Why was a hexavalent vaccine introduced into the infant schedule?

Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). Most new infections with HBV are sub-clinical or may only cause a flulike illness. However, acute infection occasionally leads to sudden and severe liver damage which can be fatal. Chronic HBV infection can result in progressive liver disease, leading to cirrhosis (development of scar tissue) in some patients and an increased risk of developing liver cancer.

In 1992, the World Health Assembly recommended that every country should have a universal hepatitis B immunisation programme by 1997. However, as the UK is a low prevalence and low incidence country for hepatitis B introducing a universal hepatitis B programme using a monovalent hepatitis B vaccine would not have been costeffective. Recently, infant combination hepatitis B vaccines (which also protect against diphtheria, tetanus, polio, pertussis and Hib) have become

available in the UK. In 2014, therefore, the Joint Committee of Vaccination and Immunisation (JCVI) re-evaluated the benefits and cost-effectiveness of a universal hepatitis B infant immunisation programme in the UK and subsequently recommended the use of the hexavalent DTaP/IPV/ Hib/HepB combination vaccine for all infants subject to securing the vaccine at a cost-effective price.

By providing hepatitis B vaccine as part of the combined infant vaccine, as well as being protected against diphtheria, tetanus, pertussis, polio and Hib, infants now have the benefit of protection against hepatitis B virus.

### What is the difference between Infanrix hexa®, Vaxelis® Infanrix®-IPV+Hib and Pediacel®?

All of these vaccines protect against the same five diseases (tetanus, diphtheria, whooping cough, polio and Hib). The main difference is that Infanrix hexa® and Vaxelis® also offer protection against hepatitis B.

#### Are the hexavalent vaccines safe and effective?

Yes. The safety profile of both hexavalent vaccines

is excellent. Any adverse events experienced are mild to moderate and are similar to those experienced following administration of the Pediacel® and Infanrix®-IPV+Hib vaccines. These may include redness, swelling and tenderness at the injection site, fever, irritability, loss of appetite, sleepiness, diarrhoea and vomiting.

Results from clinical trials show that nearly all infants given the three dose primary vaccination course of Infanrix hexa® at 8, 12 and 16 weeks of age develop protective levels of antibodies against diphtheria (100%), tetanus (100%), pertussis (100%), hepatitis B (99.5%), polio (98-100%) and Hib (96%).²

Studies also show that when a further (fourth) dose is given during the second year of life, protective levels of antibodies against all components were seen one month after receiving the dose in at least 98.4% of cases.

Similar levels of protection were seen with Vaxelis® where protective levels of antibodies against diphtheria (99.8%), tetanus (100%), pertussis (varies by component), hepatitis B (97.8%), polio (99.8% to 100%) and Hib (98%) were seen one month after completing the 3-dose primary vaccination schedule.

#### Vaccine scheduling

#### What is the routine for hexavalent vaccines?

The primary infant vaccination schedule includes a hexavalent vaccine at 8, 12 and 16 weeks of age. From 1 January 2026, children with a date of birth on or after 1 July 2024 will be offered a fourth hexavalent dose at a new 18-month routine vaccination appointment (primarily to replace the Hib component of Menitorix®, which was a Hib/MenC vaccine previously given at 12 months of age).

The first dose of the hexavalent vaccine can be given from 6 weeks if required in certain circumstances, for example travel to an endemic country. Rotavirus and MenB vaccines should also be given at the same time. The schedule should then be completed with a minimum of 4 weeks between subsequent doses of the hexavalent vaccine. Vaccine providers may decide to return a child who received the first set of primary vaccinations early back to the routine schedule and give the second set at 12 weeks. An individual decision should be made depending on the circumstances.

Note: MenB administration before 8 weeks of age is off-label and will require a patient specific direction (PSD) or prescription for its supply and administration during this period.

#### Why has a fourth dose of hexavalent vaccine been added to the schedule?

Following notification from the manufacturer in 2022 of discontinuation of the Hib/MenC vaccine (Menitorix®), which was given at 12 months of age, a review of the UK routine infant schedule was undertaken by the JCVI. Options for the necessary changes were considered and in November 2022 the JCVI issued a statement on changes to the childhood immunisation schedule. JCVI advised that a dose of meningococcal C-containing vaccine was no longer recommended in the childhood schedule at age 12 months but there was still a continued need for a Hib dose during the second year of life. As there is no Hib monovalent vaccine licensed in the UK, from 1 July 2025, a fourth dose of the hexavalent (DTaP/IPV/Hib/HepB vaccine) has been introduced into the UK schedule (replacing the previous 12 month dose of Hib/MenC). This is to be given at 18 months of age to children with a date of birth on or after 1 July 2024.

## Can hexavalent vaccines be administered at the same time as the other infant vaccines?

Yes. Hexavalent vaccines can be administered at the same time as, or at any time before or after any other vaccine. Other countries routinely offer hexavalent vaccine with the other infant vaccines, including rotavirus, pneumococcal conjugate vaccine (PCV) and MenB.

#### Can the hexavalent vaccine be given to premature infants?

Yes. Clinical data indicate that Infanrix hexa® and Vaxelis® can be given to premature infants and it is important that premature infants receive their immunisations at the appropriate chronological

age (ie age since birth, not corrected), according to the schedule. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

The immune responses seen in premature infants to these vaccines in clinical trials were generally similar to that of those of the overall study population.

In comparative clinical studies, similar rates of adverse reactions were observed in pre-term and full-term infants. However, as for pentavalent vaccines, the occurrence of apnoea following vaccination is increased in infants who were born very prematurely. Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hours.

Infants stable at discharge without a history of apnoea and/or respiratory compromise may be vaccinated in the community setting.

## What vaccine should children with incomplete, uncertain or non-UK primary immunisations be given?

Where a child has an uncertain or incomplete immunisation history (for example they have recently moved and are being transferred onto the Northern Ireland schedule), they should be vaccinated as appropriate for their age in line with the vaccination of individuals with uncertain or incomplete immunisation algorithm.

Infants and children under 10 years of age who have not completed a primary course of three doses (or four if born on or after 1 July 2024) of diphtheria, tetanus, pertussis and polio-containing

vaccine should complete their primary course with a DTaP/IPV/Hib/HepB-containing vaccine. Children born on or after 1 August 2017 who received primary vaccines without HepB (for example if given a quadrivalent or pentavalent priming vaccine), should be opportunistically offered three HepB-containing vaccines at least one month apart.

If they are at increased risk of acquisition of hepatitis B (for example, behavioural risk factors, co-existing medical conditions or individual's with learning disabilities in settings where behaviours such as biting occur) or are exposed to hepatitis B, they should be proactively offered a hepatitis B vaccine course (see the Green Book chapter 18 for further information on vaccine courses and highrisk groups).

#### Booster and catch-up doses

#### Is there a catch up programme for babies born before 1 August 2017?

No. By vaccinating all infants born on or after 1 August 2017, this will ultimately help to keep the incidence of HBV low in the population as a whole. Any individuals born before 1 August 2017 will be eligible for hepatitis B vaccine if they are identified as being at increased risk of HBV.

## Do infants given the hexavalent hepatitis B-containing vaccine need a booster dose of hepatitis B vaccine?

No. For infants who have completed a primary course of vaccination, a routine booster dose of vaccine is not required.

The full duration of protection afforded by hepatitis B vaccine is expected to be greater than 20 years.

Even though levels of vaccine-induced antibody to hepatitis B decline over time, there is evidence that immune memory persists in those successfully immunised. If they are exposed later in life, this immune memory will help to protect them against serious disease and chronic infection. If there is a significant exposure to an unknown or known hepatitis B surface antigen (HBsAg) positive source however, a booster dose of vaccine may be indicated.

For those who may become at risk of infection later in life, for example if they become health care workers, additional doses of vaccine and/or antibody testing may be required. Further details can be found in the Green Book Chapter 18. https://assets.publishing.service.gov.uk/media/68385046e0f10eed80aafad9/Hepatitis-B-green\_book-chapter-18-06-03-2025.pdf

#### Contraindications

#### What are the contraindications to receiving the hexavalent vaccine?

Hexavalent vaccines should not be administered to those who have had:

- A confirmed anaphylactic reaction to a previous dose of the vaccine OR
- A confirmed anaphylactic reaction to any component of the vaccine (this includes formaldehyde, neomycin and polymyxin).

The vaccine-specific SPC should be checked for further information. There are very few individuals who cannot receive the hexavalent vaccines. Where there is doubt, instead of withholding immunisation,

appropriate advice should be sought from a consultant with immunisation expertise or the Public Health Agency Duty Room on 0300 555 0119.

#### What are the precautions to receiving the hexavalent vaccine?

There are very few occasions when deferral of immunisation with hexavalent vaccine is required.

If an infant has a minor illness without fever or systemic upset, immunisations can still be given. If the infant is acutely unwell (for example with a fever above 38.5°C), immunisation may be postponed until they have fully recovered. This is to avoid wrongly attributing any new symptom or the progression of symptoms to the vaccine. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of the DTaP/IPV/Hib/HepB vaccine may be considered to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection and vaccination should

be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Children who have had a systemic or local reaction following a previous immunisation with DTaP/IPV/Hib/HepB or DTaP/IPV/Hib, including:

- fever, irrespective of its severity;
- hypotonic-hyporesponsive episodes (HHE);
- persistent crying or screaming for more than three hours; or
- · severe local reaction, irrespective of extent

can continue to receive subsequent doses of DTaP/IPV/Hib/HepB vaccine. Seek further advice if required.

Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation (see question on premature infants above).

#### Vaccine composition

#### Composition of Infanrix hexa® vaccine

The vial containing Hib powder also contains:

lactose anhydrous.

The pre-filled syringe containing the DTaP/IPV/ HepB suspension also contains:

- sodium chloride;
- medium 199 containing principally amino acids, mineral salts, vitamins;
- water for injections.

The vaccine contains the following adjuvants (substances added to enhance the immune response to the antigens):

- aluminium hydroxide, hydrated;
- aluminium phosphate.

The hepatitis B surface antigen component of the vaccine is produced in yeast cells (Saccharomyces cerevisiae) by recombinant DNA technology.

The vaccine may also contain traces of formaldehyde, neomycin and polymyxin which are used during the manufacturing process for inactivation and prevention of bacterial growth.

Infanrix hexa® does not contain any thiomersal or porcine gelatine.

The composition of the vaccine and excipients (other substances contained in the vaccine

besides the DTaP/IPV/Hib/HepB antigens) are listed in the vaccine manufacturer's Summary of Product Characteristics (SPC).

#### Composition of Vaxelis® vaccine

The prefilled syringe contains diphtheria, tetanus, pertussis, polio, Hib and hepatitis B antigens. The vaccine also contains the following:

Sodium phosphate water for injections

The Vaxelis® vaccine contains the following adjuvants (substances added to enhance the immune response to the antigens):

Amorphous aluminium hydroxyphosphate sulfate

Aluminium phosphate

The hepatitis B surface antigen component of the vaccine is produced in yeast cells (Saccharomyces cerevisiae) by recombinant DNA technology.

The vaccine may contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B, and bovine serum albumin which are used during the manufacturing process.

Vaxelis® does not contain any thiomersal or porcine gelatine.

A full list of vaccine excipients can be found in the Vaxelis® SPC.

#### Vaccine storage and administration

#### How should hexavalent vaccines be stored?

Infanrix hexa® and Vaxelis® should be stored between +2°C to +8°C and protected from light. Do not freeze. The vaccines must be stored in the original packaging to protect it from light, to ensure that the component parts are kept together and in order to retain the batch number and expiry date for the entire product which is printed on the outer vaccine carton.

In the event of an inadvertent or temporary temperature excursion outside of the recommended +2°C to +8°C range, stability data detailed in the Summary of Product Characteristics indicate that the vaccine components are stable at temperatures up to 25°C for 72 hours for Infanrix hexa® and 228 hours for Vaxelis®. At the end of these defined periods, the affected vaccine should be used or discarded. If further information regarding stability data is required, contact the manufacturer.

Vaccine that has exceeded 25°C or been exposed to temperatures above 8°C for more than 72

hours for Infranix hexa® or 228 hours for Vaxelis®, should be quarantined and further advice should be sought from the Trust Medicines Information Service (see https://www.publichealth.hscni.net/publications/guidance-vaccine-handling-and-storage-gp-practices Guidance on vaccine handling and storage in GP practices for contact details). For both vaccines, breaches in the cold chain should also be reported to the PHA Health Protection Duty Room.

#### How is Infanrix hexa® vaccine presented?

- The vaccine is presented in two parts and it is very important that the freeze dried Hib component is reconstituted correctly before administration.
- The DTaP/IPV/HepB component is presented as a cloudy white suspension in a pre-filled glass syringe. Upon storage, a clear liquid and a white deposit may be observed. This is a normal observation.

- The freeze dried (lyophilised) Hib vaccine is presented as a white powder in a glass vial.
- The Infanrix hexa® vaccine is supplied in single dose packs containing the syringe, vial and two needles – one for reconstitution and one for vaccine administration.

#### What are the steps involved in preparing Infanrix hexa®?

- Shake the pre-filled syringe containing the DTaP/IPV/HepB suspension in order to obtain a consistent, cloudy, white suspension.
- 2. Attach the green needle supplied to the prefilled syringe of DTaP/IPV/HepB and inject the entire contents of the syringe into the vial containing the Hib vaccine (as a powder).
- 3. Shake the vial vigorously until the powder has completely dissolved.
- 4. Withdraw the entire mixture back into the syringe.
- 5. The reconstituted vaccine appears as a slightly more cloudy suspension than the liquid component alone. This is a normal observation.
- Inspect the vaccine suspension for any foreign particulate matter and/or abnormal physical appearance. If either is observed, discard the vaccine.
- 7. Replace the green needle with the blue needle supplied and administer the vaccine intramuscularly.

#### How is Vaxelis® vaccine presented?

The DTaP/IPV/HepB/Hib component is presented as a uniform, cloudy, white to off-white suspension in a pre-filled glass syringe.

Prior to administration, the pre-filled syringe should be shaken gently in order to obtain a homogeneous, whitish, cloudy suspension.

The suspension should be visually inspected, prior to administration, for foreign particulate matter and/or variation of physical appearance. If either is observed, discard the pre-filled syringe.

#### How should hexavalent vaccines be administered?

Infanrix hexa® and Vaxelis® should be administered intramuscularly to all infants with the exception of those with a bleeding disorder who should receive the vaccine by deep subcutaneous injection to reduce the risk of bleeding. Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 of 'The Green Book'.

The preferred site of injection for infants under one year of age is the anterolateral aspect of the thigh. The current Northern Ireland immunisation schedule means that only two injections need to be given at each primary vaccine appointment under 12 months of age, therefore one injection can be given into each thigh. Should it be necessary to give more than one vaccine into the same limb, they should be given at least 2.5cm apart and the site at which each vaccine was given should be noted in the individual's records.

### Is there any change in post-immunisation care recommendations?

No. Immunisers should recommend that prophylactic paracetamol is administered when MenB vaccine is given at the same appointment as the DTaP/IPV/Hib/HepB vaccine.

For further information about administration of paracetamol, please see leaflet *Immunisations for babies up to a year old* on the PHA website: www.publichealth.hscni.net/publications/immunisation-babies-year-old-english-and-10-translations

#### Potential vaccine errors

## A dose of the hexavalent vaccine given at an interval of less than 4 weeks in error

A minimum 4-week interval is recommended between each of the three doses of hexavalent vaccine in the primary schedule. If one of these doses is given up to a week early, either inadvertently or deliberately, for example for travel reasons, then this can be counted as a valid dose and does not need to be repeated. However, no more than one dose should be given early in the three dose schedule and any doses given at less than a three week interval should be repeated four weeks after the dose given early.

## Infanrix hexa® reconstituted incorrectly and Hib component not added, meaning the child only received the DTaP/IPV/HepB component

As there is no other Hib-containing vaccine licensed in the UK, this dose will need to be discounted, and the vaccine repeated (with the Hib component correctly prepared and administered). This repeat dose should be given either at the same visit or as soon as possible after the error is realised in order to provide protection against Hib.

The incidence of local reaction to DTaP-containing vaccines may increase with additional doses.

All vaccine errors should be reported as per employer policy. It is important to establish if the error was a one-off occurrence or a systematic error that might require a look back exercise. In the latter case, please inform the PHA Health Protection Duty Room.

#### Inadvertent administration of DTaP/IPV/Hib/HepB at one year of age

If the hexavalent vaccine is inadvertently given to a

one year old child who is eligible for the 18-month appointment, this will count as a valid dose of Hib-containing vaccine and does not need to be repeated at 18 months of age. However, the child should still attend their 18-month appointment in order to receive their second dose of MMR vaccine.

## The hexavalent vaccine inadvertently given early at the 12-month appointment but then given again at the 18 months appointment

If the hexavalent vaccine is inadvertently given at the 12-month of age appointment, but then given again at 18 months of age, the parent or carer should be advised that this was repeated in error and increased localised adverse reactions (for example, a lump or redness at the site) may be experienced. The child should still receive their second dose of MMR vaccine at 18 months of age. They should continue with the routine scheduled and receive their dTaP/IPV booster vaccine at 3 years, 4 months as usual.

## The hexavalent vaccine inadvertently given at 3 years and 4 months of age

If the hexavalent vaccine is inadvertently given to children at their 3 years and 4 months of age appointment (also known as the pre-school booster) instead of the recommended dTaP/IPV vaccine, they will not require a dose of the correct vaccine to be given afterwards. This is because the hexavalent vaccine will still boost their antibodies against diphtheria, tetanus, pertussis and polio as the recommended dTaP/IPV vaccine would have done. They may be at increased risk from an adverse reaction since the antigen dose is higher in the hexavalent vaccines than in the quadrivalent pre-school vaccine.

## dTaP/IPV (or other diphtheria and tetanus-containing vaccine) inadvertently given at 18 months of age

If the dTaP/IPV vaccine (usually given at 3 years and 4 months of age), Tdap or Td/IPV vaccine is

inadvertently given at 18 months of age, then because these do not protect against Hib (or hepatitis B for babies on the selective pathway), this should be discounted and a dose of hexavalent DTaP/IPV/Hib/HepB given as soon as the error is realised. dTaP/IPV will still be required at 3 years and 4 months of age.

#### Addressing parental concerns

## What could I say to a parent or carer who is worried about having a new vaccine?

Firstly, Infanrix hexa® is not a new vaccine. It is licensed for use in 97 other countries across the world including Ireland, Canada, Australia and New Zealand. Since the vaccine was licensed for use in October 2000, approximately 150 million doses have been safely and effectively given to infants across the world with no evidence of harmful effects.

Secondly, by combining DTaP/IPV/Hib and HepB, infants can be provided with protection against six harmful diseases at the very earliest opportunity in a single injection. The five-in-one DTaP/IPV/Hib vaccine has been given to infants in the UK since 2004 and is highly efficacious and well tolerated. The hepatitis B vaccine has been used since 1981 and is also well-tolerated and highly efficacious. Numerous studies have shown that the hepatitis B vaccine can be added to the DTaP/IPV/Hib vaccine without affecting the protective response made to all the component parts or the frequency or type of adverse reactions experienced.

## What do I say to a parent or carer who is concerned about receiving a vaccine with six components in it?

It is acknowledged that some parents or carers may be concerned that their child is receiving a six component combination vaccine. While these concerns are understandable, parents should be reassured that there is no evidence to support arguments of "overloading" the immune system. From the moment a child is born, they are continually being exposed to a huge number of bacteria and viruses on a daily basis. From birth, their immune system is able to respond to both the many antigens in the environment and the relatively small number of selected antigens in vaccines.<sup>3</sup>

Additionally, before a combined vaccine is licensed for use, it must have demonstrated in pre-licensure studies that a satisfactory immune response is made to each of the combined antigens and that the rates of adverse reactions are lower or the same as they would be if the vaccines were administered separately.

## What if a parent or carer does not want to receive a vaccine with hepatitis B in it?

Healthcare professionals should ascertain what the parent's or carer's specific concerns about the hepatitis B vaccine are and address these. They should also provide them with information as to the benefits of receiving this vaccine, including information about the other diseases against which the DTaP/IPV/Hib/HepB hexavalent vaccine protects.

There is no alternative vaccine with which to adequately protect infants and young children against diphtheria, tetanus, polio, pertussis and Hib disease. The vaccines that are licensed for continuing the vaccination course at 3 years and

4 months contain lower levels of antigens and are therefore only suitable for boosting children who have already received infant priming vaccinations.

What if a parent or carer does not want their child to receive a hexavalent vaccine at 18 months to primarily protect against Hib?

Healthcare professionals should ascertain what the parent or carer's specific concerns about the hexavalent vaccine are or the timing of this dose and address these. They should also provide them with information as to the benefits of receiving it.

Studies have shown that protection against Hib from the primary vaccines given at 8, 12 and 16 weeks of age wanes during the second year of life so a fourth dose of Hib antigen, given during the second year of life (the 18-month appointment) is required to boost and lengthen protection. As there is no other Hib-containing vaccine available on the UK market, the hexavalent vaccine is the only way of ensuring this protection. This dose is required to complete the course of vaccination and provide optimal protection at the right time of life.

#### Other questions

Wasn't there a concern that protection against whooping cough is lower with three component acellular pertussis (3aP) vaccines than with five component (5aP) vaccines?

Between 2004 and 2008, the UK only used infant acellular pertussis vaccines that contained five components to ensure optimal protection against whooping cough. UK follow up of children who had received a 3aP vaccine suggested, however, that protection was equivalent to 5aP vaccines

to pre-school age. In 2008, JCVI advised that 3aP combination vaccines could be used for primary immunisation. In 2010, the WHO also reviewed all the global data on pertussis control in countries using acellular vaccines.<sup>3</sup> They concluded that acellular pertussis vaccines with three or more components have higher protective efficacy than vaccines with fewer components and did not find consistent evidence of a difference between three and five components. A 3aP component vaccine (Infanrix®-IPV+Hib), similar to Infanrix hexa®, has now been used widely in the UK since 2014.

#### **Useful links**

European Medicines Agency. Summary of the European public assessment report for Infanrix hexa®. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/infanrix-hexa

Infanrix hexa® Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2586/smpc

Vaxelis® Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/vaxelis-epar-product-information\_en.pdf UK Health Security Agency. Immunisation against infectious disease (The Green Book) Diphtheria, Tetanus, Pertussis, Polio, Hib and Hepatitis B chapters. Available at: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

Vaccination of individuals with uncertain or incomplete immunisation. Available at: https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status

#### References

- 1. Dhilllon S. DTPa-HBV-IPV/Hib vaccine (Infanrix hexa®) A Review of its Use as a Primary and Booster Vaccination. Drugs 2010: 70(8): 1021-1058 Available at: https://www.ncbi.nlm.nih.gov/ pubmed/20481658
- 2. World Health Organization (2010) Pertussis vaccines: WHO position paper. Weekly Epidemiological Record No 40 85: 385-400.



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