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Dear Colleague

INTRODUCTION OF HEXAVALENT VACCINE INTO THE ROUTINE CHILDHOOD PROGRAMME

1. We are writing to inform you that from 1 October 2017 all babies born on or after 1 August 2017 will become eligible for a hexavalent vaccine which includes protection against hepatitis B (HepB). The hexavalent vaccine will be offered in the routine childhood immunisation schedule at 8, 12 and 16 weeks of age.

2. This hexavalent vaccine, **Infanrix hexa®**, will replace the pentavalent infant vaccines, **Infanrix®-IPV+Hib** and **Pediacel®**, currently used in the routine childhood programme. This will mean babies continue to receive protection against diphtheria, tetanus, pertussis (whooping cough), polio and *Haemophilus influenzae* type b (Hib) as well as protection against Hep B.

3. This letter provides colleagues with the necessary information to introduce the hexavalent vaccine into the schedule. It sets out clinical advice on the use of **Infanrix hexa®** and information for healthcare practitioners about the administration and storage of the vaccine as well as contraindications to take into account (see Annex A). It also provides information on programme communications and workforce education materials (see Annex B).

The Green Book

4. The Hep B chapter of the Green Book (chapter 18) has been updated to reflect these changes. Healthcare practitioners are advised to familiarise themselves with the updated chapter which is available at: <https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>.

Action

5. NHS Boards, including their primary care teams, and GP practices are asked to note the arrangements outlined in this letter. We would be grateful if you could cascade this letter to others who may be affected.

**From the Chief Medical Officer
Chief Nursing Officer
Chief Pharmaceutical Officer**
Dr Catherine Calderwood
Professor Fiona McQueen
Dr Rose Marie Parr

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For action

Chief Executives, NHS Boards
Medical Directors, NHS Boards
Nurse Directors, NHS Boards
Primary Care Leads, NHS Boards
Directors of Pharmacy
Directors of Public Health
General Practitioners
Practice Nurses
Immunisation Co-ordinators
CPHMs

For information

Infectious Disease Consultants
Consultant Paediatricians
Consultant Physicians
Health Protection Scotland
Chief Executive, NHS Health
Scotland
NHS 24
Health Visitors
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Further Enquiries

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6. Thanks to you and your practice staff for your support in continuing to deliver this important routine childhood vaccination programme.

Catherine Calderwood
Chief Medical Officer

Fiona McQueen
Chief Nursing Officer

Rose Marie Parr
Chief Pharmaceutical Officer

Please always refer to the Green Book for guidance on the administration of any vaccine (<https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>). Below is some key information about the hexavalent vaccine

Why is Infanrix hexa® being introduced into the infant schedule

1. 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 flu-like 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.
2. 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. See <https://app.box.com/s/iddfb4ppwkmjtjusir2tc/file/22846051967>.

Vaccine Scheduling

3. The infant routine immunisation schedule remains unchanged at 8, 12 and 16 weeks of age.
4. The minimum interval between doses is 4 weeks. Infanrix hexa® can be administered at the same time as, or at any time before or after, other vaccines but a 4 week gap is required between a previous dose of Infanrix hexa®, Pediacel® or Infanrix –IPV+Hib®.
5. If the primary course is interrupted, it should be resumed but not repeated, allowing an interval of 4 weeks between remaining doses.

Ordering arrangements

6. Vaccine ordering is expected to open from 1 September 2017 and NHS Board vaccine holding centres will distribute Infanrix hexa® for use in the routine childhood programme in the normal way. NHS Boards will continue to meet the costs of the vaccine.

Storage of Vaccine

7. Store in a refrigerator (+2°C to + 8°C). Do not freeze and store in the original package, in order to protect from sunlight.
8. After reconstitution: an immediate use is recommended. However the stability has been demonstrated for 8 hours at 21°C after reconstitution.

Contraindications

9. There are a very few individuals who cannot receive the Infanrix hexa® vaccine. The Green Book provides detailed information on contraindications. See <https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>
10. However Infanrix hexa® 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).

Presentation

11. 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. The lyophilised (free dried) Hib vaccine is presented as a white powder in a glass vial. The vaccine is supplied in single dose packs containing the syringe, vial and two needles (green for constitution and blue for administration).

Preparation

12. The pre-filled syringe (containing the DTaP/IPV/HepB suspension) should be shaken to obtain a consistent, cloudy, white suspension.

13. The green needle should be attached to the pre-filled syringe and inject the entire contents of the syringe into the vial containing the Hib vaccine. The vial should be shaken vigorously to completely dissolve the powder. The entire mixture should be withdrawn back into the syringe.

14. This should be inspected for any foreign particulate matter and/or abnormal physical appearance. If either observed the vaccine should be discarded.

15. Lastly replace the green needle with the blue needle (supplied) and administer the vaccine intramuscularly. Please note: the reconstituted vaccine appears as a slightly more cloudy suspension than the liquid component alone. This is normal.

Administration

16. Infanrix hexa® should be administered intramuscularly. Preferred site of injection for infants under one year of age is the anterolateral aspect of the thigh. It can be given in the same thigh as the PCV vaccine at the 8 and 16 week immunisation appointments (minimum of 2.5cm apart).

17. Infants with a bleeding disorder should receive the vaccine by deep subcutaneous injection to reduce the risk of bleeding.

Existing supplies of Pediacel® and Infanrix-IPV+Hib®

18. Infants born before 1 August 2017 should complete the course with pentavalent vaccine (Pediacel® or Infanrix-IPV+Hib®).

19. In order to avoid potential wastage, NHS Boards and GP practices should aim to run down the volume of 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. Babies born before 1 August 2017 should only be given Infanrix hexa® if there is no locally held vaccine stock, no further Pediacel® or Infanrix-IPV+Hib® can be ordered from NHS board vaccine holding centres

Reporting of Adverse Events

20. Adverse events should be reported in the normal way through the Yellow Card Scheme run by the Medical Healthcare Regulatory Authority (MHRA): <https://yellowcard.mhra.gov.uk/>.

21. Chapter 8 of the Green Book provides detailed advice on managing adverse events following immunisation (AEFIs). Chapter 9 of the Green Book gives detailed guidance on which adverse reactions (ADRs) to report and how to do so.

22. Any reported adverse incidents, errors or events during or post vaccination must follow determined procedure. In addition teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.

Scottish Immunisation Call and Recall System (SIRS)

23. The Child Health system has been updated to take account of the changes and babies will be invited for immunisation by their GP Practice as normal.

Patient Group Direction (PGD)

24. A national specimen patient group direction has been developed and will be available at <http://www.hps.scot.nhs.uk/immvax/pgd.aspx> .

Communications

1. All relevant immunisation resources, such as the “*A guide to childhood immunisations up to 5 years of age*”, have been updated to support the introduction of Hep B into the routine programme.
2. The “*A guide to childhood immunisations up to 5 years of age*” booklet will be available to order from 17th July 2017 in order for it to be used with/given to babies born from August 2017 onwards. To ensure quick identification of the new booklet, the front cover contains a roundel with text stating: “Information for babies born from August 2017”.. It will be available to view/download at: www.ImmunisationScotland.org.uk/documents/6016.aspx from 1 October 2017 when the policy takes effect.
3. Translations, as well as an easy read version of the booklet will also be available online by following the link provided above. NHS Health Scotland is happy to consider requests for other languages and format. Please contact 0131 314 5300 or email nhs.healthscotland-alternativeformats@nhs.net

Educational Resources for Healthcare Practitioners

4. NHS Education for Scotland in partnership with Health Protection Scotland has produced educational resources for registered healthcare practitioners. These include training slides and further information ‘Q and A’ resources. These resources are available at <http://www.nes.scot.nhs.uk/education-and-training/by-theme/initiative/public-health/health-protection/immunisation/the-hexavalent-dtapipvhibhepb-combination-vaccine.aspx>.