

Dear Colleague

INTRODUCTION OF MENINGOCOCCAL GROUP B (MEN B) VACCINATION PROGRAMME IN 2015/16

1. We are writing to inform you that a meningococcal group B (Men B) vaccine will be added to the routine childhood vaccination programme from 1 September 2015.

2. From 1 September 2015, the Men B vaccine, Bexsero®, will be routinely offered to all babies born on or after 1 July 2015 along with the existing routine vaccinations when they attend for their childhood vaccination appointments at 2, 4 and 12-13 months.

3. When the programme begins on 1 September there will also be a one-off opportunistic catch-up for babies born on or after 1 May 2015 and who will be attending for other routine vaccinations at 3 and 4 months.

4. Fever is a common side-effect when infants are given the Men B vaccine with other routine childhood vaccines. The JCVI has therefore recommended that a total of 3 doses of infant paracetamol are given to babies after their routine vaccinations at 2 and 4 months. Infants getting the Men B vaccine as part of the one-off catch-up this year (infants at 3 and 4 months of age who were born between 1 May and 30 June 2015) will also need 3 doses of infant paracetamol to help reduce the chance of a fever developing after vaccination. The first dose of infant paracetamol will be given by the healthcare professional at the same time as the routine vaccinations and a prescription will be given to parents/guardians of the infant following vaccination for 2 further doses at 4 to 6 hourly intervals.

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

10 July 2015

SGHD/CMO(2015) 11

For action

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

For information

Chairs, NHS Boards
Infectious Disease Consultants
Consultant Paediatricians
Consultant Physicians
Health Protection Scotland
Chief Executive, Health Scotland
NHS 24
Directors of Finance, NHS Boards

Enquiries to:

Policy Issues

Sarah Paterson
3EN, St Andrew's House
Edinburgh, EH1 3DG
sarah.paterson@scotland.gsi.gov.uk

Medical Issues

Dr Nicola Steedman
3N.05, St Andrew's House
Edinburgh, EH1 3DG
nicola.steedman@scotland.gsi.gov.uk

Pharmaceutical and vaccine supply
issues

William Malcolm
Health Protection Scotland
w.malcolm@nhs.net

5. This letter provides colleagues with the necessary information to introduce this programme. It includes guidance on those infants eligible for vaccination (**Annex A**); clinical advice on the use of Bexsero®, including clear advice on the increased risk of fever from the vaccine; the use of infant paracetamol following vaccination; details of how to order the vaccine; vaccine uptake data collection arrangements; and funding arrangements (**Annex B**). Information on programme communications and workforce education materials can be found in **Annex C**.

6. The Joint Committee on Vaccination and Immunisation's (JCVI) statement about meningococcal group B disease and the Men B vaccine is available at: <https://www.gov.uk/government/publications/meningococcal-b-vaccine-jcvi-position-statement>

7. The meningococcal chapter of the Green Book '*Immunisation against infectious disease 2006*' will be updated and available at: <http://immunisation.dh.gov.uk/category/the-green-book/>

8. Scotland's successful vaccination programme brings great public health benefits. We do not underestimate the additional work required to implement the forthcoming changes to the programme and we would like to take this opportunity to thank you all very much for your efforts in delivering these programmes.

Yours sincerely,

Catherine Calderwood
Chief Medical Officer

Fiona McQueen
Chief Nursing Officer

Rose Marie Parr
Chief Pharmaceutical Officer

TIMING AND ELIGIBILITY OF MEN B VACCINE

1. The Men B vaccine, Bexsero®, will be included in the routine childhood vaccination programme from 1 September 2015. All children scheduled to receive their primary vaccines will be offered the vaccine and booster as set out in the table below:

	DOB (born on or after)	Age of infant		
		Priming dose	Priming dose	Booster
Routine cohort	01/07/2015	2 months	4 months	12-13 months
Catch-up cohort	01/05/2015 to 30/06/2015	3 months	4 months	12-13 months
		n/a	4 months	12-13 months

Catch-up cohort eligibility

Dates of birth	Recommended vaccination schedule
Those born on or after 1 May to the 30 June 2015	If third routine primary immunisation appointment due on or after 1 September then follow this schedule: 4 months and 12-13 months (1+1)
	If second routine primary immunisation appointment due on or after 1 September then follow this schedule: 3, 4 and 12-13 months (2+1)

2. Those born before 1 May 2015 are not eligible to receive the Men B vaccine.

Uncertain or incomplete vaccination status

3. For vaccination of eligible children (born on or after 1 May* 2015) with uncertain or incomplete vaccination status please refer to the meningococcal chapter of the Green Book.

** Amended from 'July' to 'May' to allow those infants who have not yet received the vaccine (e.g. recently come into the country from elsewhere), but who would have been eligible by date of birth, to still receive the vaccine (April, 2016).*

CLINICAL GUIDANCE ON VACCINATION OF INFANTS AGAINST MEN B

Recommendations for use of Bexsero®

Administration

1. Bexsero® should be given intramuscularly into the left thigh (anterolateral aspect). It is recommended that all doses of Bexsero® be given in the left thigh, ideally on their own so that any local reactions can be monitored more accurately. For individuals with a bleeding disorder, the vaccine should be given by deep subcutaneous injection to reduce the risk of bleeding.

2. When administering Bexsero®, it is important to note the information on fever and the administration of infant paracetamol.

Dosage

3. Routine vaccination schedule (infants born on or after 1 July 2015) recommends 0.5mL Bexsero® with their routine vaccinations as outlined in **Annex A**

4. Catch-up cohort vaccination schedule (infants born on or after 1 May 2015 to 30 June 2015) recommends 0.5mL Bexsero® with their routine vaccinations as outlined in **Annex A**.

Infant paracetamol

5. In clinical vaccine trials, the most common adverse reaction observed in infants and children under 2 years of age was a high rate of fever (>38°C) when Bexsero® was administered at the same time as other routine childhood vaccines. As a result, the JCVI recommended the use of prophylactic infant paracetamol when infants receive Bexsero® at the same time as other routine childhood vaccines such as DTaP/IPV/Hib at 2, 3 and 4 months of age. As these vaccines are not administered as part of the 12-13 month booster vaccines, there is no additional requirement to offer infant paracetamol at the same time.

6. A 2.5ml dose of infant paracetamol oral suspension (120mg/5ml) will be given orally at the time of vaccination by the healthcare professional administering the vaccine. A prescription for infant paracetamol oral suspension (120mg/5ml) will be given to the parent following vaccination to allow a further 2 doses to be given at 4-6 hourly intervals. This should reduce the likelihood or intensity of fever without diminishing the immune response.

Contraindications

7. There are very few infants who cannot receive Bexsero®. When in doubt, appropriate advice should be sought from an immunisation co-ordinator rather than withhold vaccination. Bexsero® should not be given to infants who have had:

- A confirmed anaphylactic reaction to a previous dose of the vaccine, or
- A confirmed anaphylactic reaction to any constituent or excipient of the vaccine.

Immunosuppression and HIV infection

8. Bexsero® can be given to infants with HIV infection (regardless of CD4 count) or immunosuppressed in accordance with the routine schedule.

Concomitant administration with other vaccines

9. Bexsero® can be given at the same time as other vaccines administered as part of the routine childhood vaccination programme. It is recommended that Bexsero® be administered on its own in the left thigh. Other routine vaccines should be administered other limbs. Where it is not practically possible to administer Bexsero® on its own, other routine vaccines can be administered in the left thigh at the same time as Bexsero® rather than delaying immunisations. If more than one vaccine needs to be administered in the same limb, then it must be given at least 2.5cm apart. The sites at which each vaccine was given should be noted in the individual's health records.

Consent

10. See Chapter 2 of *Immunisation against infectious disease* ('the Green Book') <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Pharmacy Issues

Vaccine brand name and supplier

11. Bexsero® is supplied by GlaxoSmithKline. Please note that the packaging may still say Novartis.

Presentation

12. Bexsero® is supplied as a prefilled fixed syringe in a **pack of 10**, without needles.

13. The vaccine is presented as a clear, colourless liquid, free of visible particles, for intramuscular administration. The vaccine is ready to use (no reconstitution or dilution is required) and is to be administered intramuscularly without mixing with any other vaccines or solutions.

14. Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension. Before use, the pre-filled syringe should be well shaken in order to form a homogenous suspension. The vaccine should be visually inspected for particulate matter and discolouration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

15. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Vaccine supply

16. Bexsero® should be ordered in the usual way from NHS Board vaccine holding centres. NHS Board vaccine holding centres should use the existing ordering arrangements to place orders for Bexsero®.

17. Centrally purchased vaccines for the national vaccination programme should only be used for those eligible under the national programme.

Liquid infant paracetamol supply

18. The infant paracetamol suspension for use within the practice will be ordered using GP10a stock order system but the oral syringes and bottle adaptors if required will be centrally procured and supplied to GP practices by NHS boards

Storage

19. Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines are sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Do not freeze. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

Vaccine stock management

20. Please ensure sufficient fridge space is available for the new vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. No more than 2 weeks of stock is recommended, and higher stock levels should be reduced to this level. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.

21. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. Local protocols should be in place to reduce vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.

22. Any cold chain failures must be documented and reported to local NHS Board using local reporting arrangements.

Reporting of adverse reactions

23. Because Bexsero® is a newly licensed vaccine, it is subject to additional monitoring under the black triangle labelling. All suspect adverse reactions to vaccines occurring in children or in individuals of any age after vaccination with vaccines labelled with a black triangle should be reported to the MHRA using the yellow card scheme (www.yellowcard.gov.uk).

24. It is recommended that all doses of Bexsero® be given in the left thigh, ideally on their own so that any local reactions can be monitored more accurately.

25. 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.

26. 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.

Surveillance

27. The programme will be carefully monitored by Health Protection Scotland and Medicines and Healthcare Products Regulatory Agency.

Health Information Systems (SIRS and GP)

28. The Scottish Immunisation Recall System (SIRS) will be adapted to provide full call & recall functionality for Men B vaccination for children born on or after 7 July 15. For children born from 1 May 15 to 6 July 15, lists of eligible children (based on birth date) will be sent to relevant treatment centres by child health/SIRS departments, so that Men B can be offered at children's 2nd and/or 3rd primary vaccination appointments.

29. NHS Boards should ensure that vaccine batch numbers are entered into the SIRS system, to enable rapid identification of specific children who have been given a particular batch.

30. GP IT systems will also be adapted to accommodate the new vaccine programme changes.

Personal Child Health Record (the 'Red Book')

31. Arrangements have been made for the Red Book record of childhood vaccinations to be amended to reflect the changes to the childhood schedule, including Men B vaccination. It is important that the information about vaccinations given are recorded in the Red Book.

Patient Group Directives

32. The requirement for Patient Group Directions is described in HDL(2001)7 available from http://www.sehd.scot.nhs.uk/mels/HDL2001_07.HTM. Use of PGDs for administration of vaccines is described in the 'Immunisation against Infectious Disease' book: <http://media.dh.gov.uk/network/211/files/2012/07/Chapter-5.pdf>

33. A specimen PGD for use with Men B vaccine, Bexsero® has been produced by HPS to assist NHS Boards. This is available on-line at the following link: <http://www.hps.scot.nhs.uk/immvax/pgd.aspx>

Local data management and monitoring vaccine uptake

34. Maintenance of comprehensive and accurate data is a key factor determining the effective delivery of all vaccination programmes.

35. As with other national immunisation programmes, ISD will calculate and publish Men B vaccination uptake rates for each NHS Board and nationally using data held within SIRS.

Funding arrangements

36. The Scottish Government will fund the full cost of the Men B vaccine for this programme, as well as other central costs relating to surveillance and IT. Invoices for Men B vaccine will be paid directly by the Scottish Government.

37. NHS board vaccine holding centres will be required to confirm vaccine deliveries to Scottish Government. Details on this process will be shared with NHS boards before the start of the programme.

Contractual Arrangements

38. The new Men B DES reflects that claims for payment can be made for the Men B vaccination. This will be available on SHOW once published. (See <http://www.show.scot.nhs.uk/publications/>)

39. As previously notified, the Scottish Government is meeting the vaccine purchase costs associated with this programme and NHS Boards are meeting the delivery costs, including GP costs, from their baseline resources. We ask NHS Boards to support GP Practices across the whole vaccination programme to at least the same level as previous years.

COMMUNICATIONS AND INFORMATION FOR PARENTS AND HEALTH PROFESSIONALS

Communications

1. The public information leaflet “*Help protect your baby against Men B*” will be distributed locally, and can also be accessed here: www.immunisationscotland.org.uk/menb. The routine childhood immunisations booklet: ‘*A Guide to childhood Immunisations up to 5 years of age*’ will also be updated with Men B information.
2. These resources are available in Urdu, Chinese and Polish, and in Easy Read format. NHS Health Scotland is happy to consider requests for other languages and formats. Please contact 0131 314 5300 or email nhs.healthscotland-alternativeformats@nhs.net
3. Further information about the full range of vaccinations and vaccines in Scotland is available on the public information website: www.immunisationscotland.org.uk

Educational resources for registered healthcare practitioners

4. NHS Education in partnership with Health Protection Scotland has produced educational resources for registered healthcare practitioners. These include training slides with notes and a ‘question and answer’ resource. These can be found at:

<http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/meningococcal-b-disease-for-infants-aged-from-two-months.aspx>