Chief Medical Officer and Public Health Directorate

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The Scottish Government

Dear Colleague

INTRODUCTION OF PREVENAR 13® INTO THE ROUTINE CHILDHOOD IMMUNISATION PROGRAMME

1. This letter provides information about the Scottish Government's plans to replace the pneumococcal conjugate vaccine Prevenar® (which contains antigens against seven pneumococcal strains) with Prevenar 13® (which contains antigens against thirteen strains).

2. Replacing Prevenar® with Prevenar 13® will broaden the protection against pneumococcal disease. Scotland, along with other parts of the UK, will be one of the first countries in the world to introduce this new vaccine and it reflects our continued commitment to improving our vaccination programme.

ACTION

3. Healthcare providers should now familiarise themselves with the information that is available about Prevenar 13®. The attached annex provides some background, and a new chapter of the Green Book has also been produced by the Department of Health. This can be accessed on line at the following link: http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/dh_4097254. (Please note that the DH website currently includes both the current and revised pneumococcal chapters and will do so until the vaccine changeover takes effect – colleagues should ensure that they consult the revised chapter for any Prevanar 13® advice).

4. Healthcare providers should be preparing local PGDs for the new vaccine. A model PGD has been prepared and is available on the Health Protection Scotland website at: http://www.hps.scot.nhs.uk/immvax/publicationsdetail.aspx?id=43950

5. Vaccine holding centres should place orders for supplies of Prevenar 13® with Movianto from **1st March 2010**.

From the Chief Medical Officer And Chief Pharmaceutical Officer
Dr Harry Burns MPH FRCS(Glas) FRCP(Ed) FFPH
Professor Bill Scott BSc MSc FRPharmS

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Addresses

For action
Chief Executives, NHS Boards
General Practitioners
Practice Nurses
Health Visitors
Directors of Pharmacy
Immunisation Co-ordinators
Vaccine Holding Centres
CPHMs
Directors of Public Health
Medical Directors, NHS Boards
District Nurses

For information
Nurse Directors, NHS Boards
Specialists in Pharmaceutical Public Health
Infectious Disease Consultants
Consultant Paediatricians
Consultant Physicians
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Further enquiries

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6. GP practices should liaise with holding centres locally in relation to orders and stock. **All GP practices should be using Prevenar 13® in the routine immunisation programme by 1 April 2010.**

7. Once stocks of Prevenar 13® begin to be distributed to healthcare providers they should be administered to children in preference to Prevenar® to ensure that as many children as possible can benefit from the additional protection provided by the replacement vaccine.

Yours sincerely

Harry Burns *Bill Scott*

Dr Harry Burns
Chief Medical Officer

Professor Bill Scott
Chief Pharmaceutical Officer

PREVENAR 13®

Vaccination against pneumococcal infection

1. Prevenar was introduced in 2006 and offered protection against seven strains of pneumococcal bacteria (4, 6B, 9V, 14, 18C, 19F and 23F). Since its introduction, we have seen a fall in the number of cases of invasive pneumococcal disease in children aged 5 and under caused by these seven pneumococcal strains.

2. Prevenar 13® offers protection against the same seven strains as Prevenar® plus an additional six pneumococcal strains (1, 3, 5, 6A, 7F and 19A). The incidence of pneumococcal disease caused by these six additional strains has recently increased.

Timing

3. Prevenar 13® will be available to order from Movianto from 1st March 2010 and vaccine holding centres should start placing orders for the new vaccine from this time. With an allowance of time for distribution across the country, **all GP practices are expected to be using only Prevenar 13® in the routine childhood programme by 1st April 2010.**

Routine Childhood Immunisation Schedule

4. The routine vaccination schedule will remain unchanged.

5. The primary course of pneumococcal conjugate vaccine (PCV) vaccination consists of two doses of Prevenar 13® with an interval of two months between each dose. The recommended age for vaccination is at two and four months of age. If the primary course is interrupted, it should be resumed but not repeated, allowing an interval of two months between doses. For infants who began their primary immunisation course with Prevenar®, the course can be completed with Prevenar 13®.

6. A reinforcing (booster) dose of PCV (Prevenar 13®) is recommended at 13 months of age for children who have received a complete primary course of two PCVs. It should be given one month after the Hib/MenC vaccine. When this is not feasible or practical the booster can be given at the same visit as the Hib/MenC vaccine as recommended by the JCVI and as stated in the revised Green Book advice.

7. Prevenar 13® will be a direct replacement for the existing PCV vaccine (Prevenar®) and will follow the same three dose schedule, i.e. doses offered at 2, 4 and 13 months of age. This means that apart from using a replacement vaccine, the vaccination schedule (see below) remains unchanged.

Children who have already started but not completed their primary course of pneumococcal vaccination

8. Prevenar 13® will be a direct replacement for the PCV currently used in the routine programme, Prevenar®. Children who have already received one or two doses of Prevenar® should complete their vaccination course with Prevenar 13® according to the routine vaccination schedule, e.g.

- A child who has received one dose of Prevenar® at two months will be offered a dose of Prevenar 13®at four months of age, and a further dose at 13 months.

- A child who has received Prevenar® at two and four months of age will be offered Prevenar 13®at thirteen months of age.

Vaccination of children with unknown or incomplete vaccination status

9. Unless there is a reliable history of previous immunisation, individuals should be assumed to be unimmunised. A child who has not completed the primary course (and is under one year of age) should have the outstanding doses at appropriate intervals (see above). A child aged one and under two years of age should have a single dose of Prevenar 13®. For infants who began their course of immunisation by receiving Prevenar®, the course should be completed with Prevenar 13®.

Vaccination of children in risk groups

10. Children in risk groups (which are defined in the Pneumococcal Chapter (Chapter 25) of the Green Book[1]) should be vaccinated according to the routine schedule as below. Clinicians may wish to consider offering one dose of Prevenar 13® opportunistically to those at risk children aged under 2 years who have already completed the course of three doses of Prevenar®. Children in these groups should also receive pneumococcal polysaccharide vaccine at the appropriate age as described in Chapter 25 of the Green Book. Advice on the immunisation of children under five years of age in risk groups who are unimmunised or have missed immunisations is also given in Chapter 25 of the Green Book.

Administration

11. Vaccines are routinely given into the upper arm in children and adults or the anterolateral thigh in infants under one year of age. This is to reduce the risk of localised reactions, which are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding.

12. Pneumococcal vaccines can be given at the same time as other vaccines such as DTaP/IPV/Hib, MMR, MenC, Hib/MenC and influenza. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Pharmacy Issues

13. Prevenar 13® is manufactured by Pfizer (formally Wyeth).

Medical Information: Tel: 01737 331111; Fax: 01737 332507;
Email:MedInfoUK@Pfizer.com.

14. The vaccine is in the same presentation as Prevenar®; each pack containing 10 single dose pre-filled syringes. A single dose of Prevenar 13® is 0.5ml. Needles are not included. The dimensions of a pack containing 10 doses of Prevenar 13® are: 100mm x 56mm x

[1] http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/dh_4097254

44mm. A picture of the new pack and syringe design can be found at: www.wyethvaccines.co.uk/products.

15. Prevenar 13® has been licensed by the European Medicines Agency (EMEA).

16. The Summary of Product Characteristics (SPC) and the Product Information Leaflet (PIL) are available at: www.wyethvaccines.co.uk/products

Vaccine Supply

17. Orders for Prevenar 13® will be taken from 1st March 2010. Orders can be placed through Movianto UK in the usual way.

18. **Please note that surgeries must place an order for Prevenar 13® with vaccine holding centres in order to receive a delivery of the vaccine.** The vaccine is not being distributed on automatic allocation.

19 Please note that if central stocks of Prevenar® are exhausted before 1st March 2010, any orders received will be fulfilled with Prevenar 13®.

Storage of vaccines

20. 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. Effectiveness cannot be guaranteed for vaccines unless they have been stored at the correct temperature. 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.

Patient Group Directions (PGD)

21. A locally agreed PGD should be drafted to support the administration of Prevenar 13®. A model PGD template has been produced and is available on the Health Protection Scotland website at http://www.hps.scot.nhs.uk/immvax/publicationsdetail.aspx?id=43950. This, plus the SPC and PIL, can be used to support the development of a locally agreed PGD.

Information Resources

22. The following information materials, produced by Health Scotland, cover the pneumococcal vaccination programme.

A guide to childhood immunisation for babies up to 13 months of age
http://www.healthscotland.com/documents/1333.aspx

A guide to immunisations at 12 to 13 months
http://www.healthscotland.com/documents/3782.aspx

More detailed or technical information about the vaccination is available from the revised Green Book chapter as detailed above.

Recording Vaccinations Administered

23. The main GP IT suppliers have been made aware of this change and new READ CODES have been issued to support the changeover. If your IT system has not been updated to allow you to record a Prevenar 13® vaccination please contact your IT supplier directly so they can update your system accordingly.

Reporting of Adverse Reactions

24. Prevenar 13® vaccine carries a black triangle symbol (▼).This is a standard symbol added to the product information of a vaccine during the earlier stages of its introduction, to encourage reporting of all suspected adverse reactions.

25. Doctors, nurses, pharmacists or parents can report a suspected adverse reaction to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme (www.yellowcard.gov.uk) .

26. The safety of the vaccine was assessed in controlled clinical studies and the safety profile of Prevenar 13® was similar to Prevenar®. For Prevenar®, very common or common reactions reported included decreased appetite; pyrexia; irritability; any injection-site erythema: induration/swelling or pain/tenderness; somnolence; poor quality sleep. Reports of all adverse reactions can be found in the summary of product characteristics for Prevenar 13®.

Vaccine Stock Management - Disposal of Local Stocks of Prevenar®

27. Locally agreed protocols for the disposal of vaccines should be followed for any remaining Prevenar® once supplies of Prevenar 13® have been received.

Funding Arrangements

28. As this is a direct replacement for an existing vaccine, there is no impact on payments to GPs from this change to the routine immunisation programme.