From the Chief Medical Officer
Dr Michael McBride

Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

HSS(MD) 11/2013

For Action:

Chief Executives, Public Health Agency/Health & Social Care Board/HSC Trusts/NIAS
GP Medical Advisers, Health & Social Care Board
All General Practitioners and GP Locums (*for onward distribution to practice staff)*

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Your Ref:
Our Ref: HSS(MD) 11/2013
Date: 30 April 2013

Dear Colleague

INTRODUCTION OF ROTAVIRUS VACCINE FOR BABIES AGED 2 AND 3 MONTHS FROM 1 JULY 2013 INTO THE ROUTINE CHILDHOOD VACCINATION PROGRAMME

ACTION REQUIRED

Chief Executives must ensure that this information is drawn to the attention of all staff involved in the childhood vaccination programme, to enable them to respond accordingly.

The HSCB must ensure that this information is cascaded to all General Practitioners immediately.

Introduction

1. The purpose of this letter is to advise you of the introduction of rotavirus vaccine for babies aged 2 and 3 months from **1 July 2013** into the routine childhood vaccination programme and to alert you to a number of planned changes to vaccination programmes that will be introduced during 2013. They are:

   - from **1st June 2013**, changes to the current schedule for administering the **Men C conjugate** vaccine;
   - from **1st July 2013**, the introduction into the childhood immunisation schedule of a vaccine to protect babies against **rotavirus**;
   - from **1st October 2013**, the introduction of a **shingles** vaccine for people aged 70 years (routine cohort) and 79 years (catch-up cohort) to protect against herpes zoster; and,
   - From **1st October 2013** the **Flu vaccination** programme will be extended to cover some **pre school** children and all children in **year 6 in primary school**. This is the first step in the phased introduction of the flu vaccination programme to all children aged two to 16 inclusive.

2. These changes to the national vaccination programme have been recommended by the Joint Committee on Vaccination and Immunisation (JCVI) to improve the overall level of protection against preventable diseases. A table summarising these changes is attached at Annex B.

3. We will be writing to you separately about each of these changes in due course. This letter sets out the details of the introduction of the rotavirus vaccine into the vaccination schedule.

Introduction of the rotavirus vaccine into the routine vaccination programme

Important points to note:

- **Rotavirus Vaccine is a LIVE ORAL vaccine (please note Annex A Para 16 – 21)**
- **Unlike other childhood vaccines there are UPPER age limits for this vaccine, above which it MUST NOT be given (see Annex A Para 12-15)**
- **There is no 'catch-up' for this vaccination programme. Those older than 2 months in July will not be offered the vaccine.**

4. Rotavirus is a very common and potentially serious gastrointestinal infection in young babies.

5. The new vaccine will be included in the childhood vaccination programme from **1st July 2013**.

6. The vaccine should be offered routinely to all babies aged 2 months and again at 3 months (that is, two doses four weeks apart) when they attend for their first and second routine childhood immunisations.

7. Detailed clinical guidance for healthcare professionals is set out in ***Annex A*** to this letter.

8. A new chapter on rotavirus, including clinical advice and information about the vaccine, has been included in *Immunisation against infectious disease 2006 (the Green Book)*, which will be available to read at: Green Book Chapter

   JCVI's statement about rotavirus and rotavirus vaccine is available at: JCVI Statement

9. Northern Ireland's childhood vaccination programme brings great benefits to the health of children. We do not underestimate the additional work brought about by this change to the programme and we would like to take this opportunity to thank all involved in delivering the programme for their continuing hard work.

Yours sincerely

DR MICHAEL MCBRIDE **Chief Medical Officer**	**MRS CHARLOTTE MCARDLE** **Chief Nursing Officer**	**DR MARK TIMONEY** **(Acting) Chief Pharmaceutical Officer**

CIRCULATION LIST

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Assistant Director Public Health (Health Protection), Public Health Agency
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Assistant Director of Pharmacy and Medicines Management, Health & Social Care Board
Directors of Pharmacy HSC Trusts
Director of Social Care and Children, HSCB
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All Community Pharmacies
Medical Directors, HSC Trusts *(for onward distribution to all Consultant Obstetricians, Paediatricians and other relevant staff)*
Directors of Nursing, HSC Trusts *(for onward distribution to all Community Nurses, and Midwives)*
Directors of Children's Services, HSC Trusts
RQIA (*for onward transmission to all independent providers including independent hospitals*)
Regional Medicines Information Service, Belfast HSC Trust Regional Pharmaceutical Procurement Service, Northern HSC Trust

This letter is available on the DHSSPS website at
www.dhsspsni.gov.uk/index/phealth/professional/cmo_communications.htm

Annex A

CLINICAL GUIDANCE ON IMMUNISATION OF INFANTS AGAINST ROTAVIRUS

1. This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI), the UK's independent panel of immunisation experts. Full guidance can be found in the new chapter on rotavirus now included in *Immunisation against infectious disease* ('the Green Book') at the following generic link: Green Book Chapter

Background to the introduction of rotavirus vaccine

2. Nearly all children will have at least one episode of rotavirus gastroenteritis before reaching five years of age. Approximately 380 children under five years of age were hospitalised in Northern Ireland in 2012. Although deaths from rotavirus in the UK are rare and are difficult to quantify accurately, there are likely to be approximately three to four a year. Rotavirus infection in children and adults leads to severe diarrhoea, vomiting, stomach cramps, dehydration and mild fever and is likely to last approximately three to eight days.

3. In the UK there are several circulating strains of rotavirus, with G1P[8] the most abundant type, although distribution of the strains changes over time. Rotavirus is highly contagious and transmission by the faecal-oral route is most frequent, although respiratory transmission may also occur. Although good hygiene measures can help prevent spread of the disease, for example proper hand washing after going to the toilet or after nappy changing, the robustness of rotavirus and the low minimal infectious dose of 10 – 100 virus particles, renders rotavirus readily transmissible and makes standard sanitary measures to halt transmission of the virus relatively ineffective.

4. Rotavirus infection in the UK is seasonal, occurring mostly in winter and early spring (January to March). People of any age can be infected by rotavirus but most infections occur in infants and children between one month and four years of age. Infections are often recurrent, and many children experience infection on one or more occasions by three years of age. Infection in newborns is common but tends to be either mild or asymptomatic because of protection by circulating maternal antibodies. Once someone has had a rotavirus infection they usually develop immunity although it may be short lived.

5. JCVI advised in 2009 that the licensed rotavirus vaccines would have a significant impact on reducing gastroenteritis in young children, and that the UK health departments should introduce the vaccines if they could be procured at a cost effective price. This advice was reiterated in 2011 following consideration of a further cost-effectiveness study.

6. Rotavirus vaccines, including the Rotarix® vaccine which will be used in the UK, are already used to routinely vaccinate children in the US and many other countries. In the US, studies have shown that rotavirus-related hospital admissions for young children have reduced by more than two thirds since rotavirus vaccination was introduced.

7. The rotavirus immunisation programme in the UK will prevent a significant number of young infants from developing this infection. A published study estimated that vaccinating a birth cohort of infants in England and Wales may prevent around 90,000 infections, about 10,000 hospitalisations and around two deaths due to rotavirus in that cohort over the first five years of life. It may also provide some additional protection to the wider population through herd immunity.

Timing

8. The vaccine will be included in the childhood immunisation programme from **1ST July 2013**. All children scheduled to receive their primary vaccines at ages 2 and 3 months should be offered the vaccine, that is, two doses four weeks apart.

Recommendations for use of the vaccine

Administration

9. Rotarix® vaccine is given orally. **It must not be injected.**

10. If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit. There are no restrictions on an infant's consumption of food or drink before or after vaccination.

11. Full guidance on the administration technique is included in the relevant chapter of the Green Book

Dosage

Infants aged 6 weeks to under 15 weeks

12. The minimum age for the first dose of Rotarix® is 6 weeks 0 days, the maximum age for dose one is 14 weeks and 6 days.

Infants aged 15 weeks to under 24 weeks

13. Vaccination with Rotarix® should not be initiated for infants aged 15 weeks and 0 days or older. Infants who have received their first dose of vaccine under 15 weeks and 0 days of age can receive their second dose of Rotarix®, which must be given with a minimum interval of 4 weeks and by 23 weeks and 6 days of age.

Infants aged 24 weeks or older

14. Rotarix® vaccine should not be given to an infant who is 24 weeks and 0 days of age or older.

15. It is preferable that the full course of two doses of Rotarix® be completed before 16 weeks of age, allowing at least four weeks between the first and second dose. Infants older than 15 weeks of age, who have not received a first dose of vaccine, should not be offered Rotarix®. Infants who receive the first dose before week 15 should complete the course by 24 weeks of age. If the course is interrupted, it should be

resumed **but not repeated**, in line with the restrictions on timings above.

Contraindications

16. There are very few infants who cannot receive rotavirus vaccine. Where there is doubt, appropriate advice should be sought from an immunisation coordinator or consultant in health protection rather than withholding vaccination.

17. Rotarix® should not be given to:
    - infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine,
    - infants with a confirmed anaphylactic reaction to any components of the vaccine,
    - infants with a previous history of intussusception,
    - infants over 24 weeks of age
    - infants with Severe Combined Immunodeficiency (SCID) disorder
    - infants who have a congenital malformation of the gastrointestinal tract that could predispose them to intussusception
    - infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency

18. Administration of rotavirus vaccine should be postponed in infants:
    - suffering from acute severe febrile illness
    - suffering from acute diarrhoea or vomiting. This is to make sure that the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness of the vaccine.

Immunosuppression and HIV infection

19. Rotavirus vaccine should not be administered to infants known to have severe combined immunodeficency (SCID). There is a lack of safety and efficacy data on the administration of rotavirus vaccine to infants with other immuno-suppressive disorders. Administration in these cases should be considered in relation to the risks and benefits of vaccination. Where appropriate, advice should be sought from the clinician responsible for the treatment and care of the immunocompromised child.

20. However, the safety profile between Rotarix® and placebo is similar in infants with HIV infection and therefore vaccination is supported in HIV infected infants. Additionally, infants with unknown HIV status, but born to HIV positive mothers, should be offered vaccination.

21. There is a potential for transmission of live attenuated vaccine in Rotarix® from the infant to severely immuno-compromised contacts through faecal material. Therefore, severely immuno-compromised individuals should avoid close contact with infants who have had the rotavirus vaccine for at least 14 days. Additionally, those in close contact with recently vaccinated infants should observe good personal hygiene. When an immuno-compromised contact cannot avoid close contact with the infant then the risks and benefits of immunisation need to be considered, including the likelihood and consequences of an un-immunised child developing natural infection. Where appropriate, advice should be sought from the clinician responsible for the treatment and care of the immunocompromised person.

Concomitant administration with other vaccines

22. Rotavirus vaccine can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme (including BCG) and so should ideally be given at the scheduled two month and three month vaccination visits (see above).

Consent

23. See Chapter 2 of *Immunisation against infectious disease* ('the Green Book') http://immunisation.dh.gov.uk/green-book-chapters/chapter-2/

Pharmacy issues

Vaccine brand name and manufacturer

24. Rotarix® – manufactured by GlaxoSmithKline.

Presentation

25. Rotarix® is supplied as an **oral** suspension in pre-filled **oral** applicator.

26. The vaccine is presented as a clear, colourless liquid, free of visible particles, for **oral** administration.

27. The vaccine is ready to use (no reconstitution or dilution is required).

28. The vaccine is to be administered **orally** without mixing with any other vaccines or solutions.

29. The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.

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

Vaccine supply

31. Stocks of Rotarix® vaccines will be supplied via designated Trust Pharmacy Departments. Trust Pharmacy Departments will be able to order supplies of Rotarix® vaccine via Movianto Ireland.

    Further information on supply arrangements and stock availability will be issued to Trust Pharmacy Departments, by the Regional Pharmaceutical Procurement Service (Tel: 028 9442 4089).

Storage

32. Vaccines should be stored in the original packaging at +2˚C to +8˚C and protected from light. All vaccines may be sensitive to some extent to heat and cold. 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.

33. The vaccine should be used immediately after opening

Vaccine stock management

34. Please ensure sufficient fridge space is available for the new vaccine. GPs should not overstock the vaccine. Additional supplies can be obtained using the normal ordering procedure.

35. 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.

36. Any cold chain failures must be documented and reported to the Public Health Agency.

Reporting of adverse reactions

37. Suspected adverse reactions (ADR) to vaccines should be reported via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). Chapter 9 of the Green Book gives detailed guidance which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation.

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

Intussusception

39. Intussusception is a naturally-occurring condition, with a background annual incidence of around 120 cases per 100,000 children aged under one year (ref: https://extranet.who.int/aim_elearning/en/vaccines/rota/pdf/Acute_intussusception_WHO.pdf)

    The peak risk is at about 5 months of age, it is for this reason that rotavirus vaccine must be given by the ages stated in sections 12-15.

40. Research from some countries[1],[2] suggests that Rotarix may be associated with a very

[1] Intussusception risk and health benefits of rotavirus vaccination in Mexico and Brazil. Patel MM, López-Collada VR, Bulhões MM, De Oliveira LH, et al. N Engl J Med. 2011 Jun 16;364(24):2283-92.

[2] Velázquez FR, Colindres RE, Grajales C, et al. Pediatr Infect Dis J. 2012 Jul;31(7):736-44. doi: 10.1097/INF.0b013e318253add3. Postmarketing surveillance of intussusception following mass introduction of the attenuated human rotavirus vaccine in Mexico.

small increased risk of intussusception, possibly 2 cases per 100,000 first doses given, and the Rotarix prescribing information includes this as a possible side effect. Even with this small potential risk, the benefits of vaccination in preventing the consequences of rotavirus infection outweigh any possible side effects.

Surveillance

41. The programme will be carefully monitored by the Public Health Agency, and the Medicines and Healthcare products Regulatory Agency.

Child Health System

42. The Child Health System has been upgraded to accommodate this new vaccination programme.

Vaccine uptake data collection

43. Monthly automated surveys from GP systems will run from the start of the programme (1st July 2013) so that July data (1/7/13 to 31/7/13 inclusive) will be collected in early August 2013. A review will be conducted in March 2015 on continuing the sentinel collection. This data collection will run in parallel to a proposed COVER data collection.

Funding and service arrangements

44. Changes confirmed to the GP contract for 2013/14 introduce a new item of service fee of £7.63 for a completed course of rotavirus vaccine for infants. The Statement of Financial Entitlements which will be published shortly will contain the provisions (Section 12) on eligibility for payment to GMS contractors to commence from 1 July 2013.

Communications and information for parents and health professionals

45. The existing immunisation information booklets will be amended to include details of the new vaccines and to bring them into line with the new schedule. They will be available from the Public Health Agency in the usual way. In addition to the new Green Book chapter, there will be a Q&A factsheet for health professionals.

46. Materials for health care professionals will shortly be avilable at: http://www.publichealth.hscni.net/publications

47. Materials for parents will shortly be avilable at: http://www.publichealth.hscni.net/publications

Annex B

Summary of planned changes to the vaccination schedule in 2013/14

Programme	June 2013	July 2013	August 2013	Sept 2013	Oct 2013	Nov 2013	Dec 2013
Men C vaccine: remove one primary dose	√						
Rotavirus vaccine introduced		√					
Men C vaccine: adolescent dose introduced through schools				√*			
Shingles vaccine: programme begins (including catch-up)					√		
Flu vaccine for some pre-school children and P6 pupils introduced					√		

*This can take place at any point in the 2013/14 academic year. In practice, it is most likely to be administered in schools in the spring 2014 term.