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Dear Colleague

MENINGOCOCCAL ACWY (MEN ACWY) VACCINATION PROGRAMME: UNIVERSITY FRESHERS AND ADOLESCENTS AGED 14-18.

1. We are writing to inform you of the introduction of a Men ACWY vaccine into the national vaccination programme this year from 1 August 2015. This programme is required to respond to a sudden, rapid and accelerating increase in cases of meningococcal group W (Men W) in the UK. The aim of the Men ACWY vaccination programme is to provide individual protection to those at higher risk of infection and to reduce carriage of the four strains of meningococcal bacteria to provide herd immunity to the wider population.

- 2. There will be two aspects to the programme:
 - The Men ACWY vaccine will replace the Men C vaccine in the existing time-limited freshers programme (for first time university entrants under the age of 25 who haven't already received Men ACWY vaccine in school).
 - An urgent one year catch-up of all 14-18 year olds (including the routine S3 cohort) with Men ACWY vaccine will be delivered by both NHS Boards and GP Practices over one year (2015/16) from 1 August 2015. Going forward, the Men ACWY vaccine will replace the Men C vaccine used in the routine adolescent programme in S3.

3. This letter provides the information you need to implement the Men ACWY programme, including guidance on timing and eligibility of vaccination (**Annex A**). It also contains clinical advice on the use of the Men ACWY vaccines (Nimenrix® and Menveo®), details of how to order the vaccine and funding arrangements (**Annex B**). Information on communications and education materials can be found in **Annex C**.

4. The meningococcal chapter of the Green Book 'Immunisation against infectious disease', once updated, will be available at: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

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) 10

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

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5. We do not underestimate the additional work brought about by the introduction of this programme, and would like to take this opportunity to thank all involved in delivering the programme for their continuing hard work.

Yours sincerely,

Catherine CalderwoodFiona McQueenRose Marie ParrChief Medical OfficerChief Nursing OfficerChief Pharmaceutical Officer

TIMING AND ELIGIBILITY OF MEN ACWY VACCINATION

Timing

Freshers Programme

1. The freshers Men ACWY programme will commence from 1 August 2015 and will be delivered by General Practices. It is important that eligible university entrants including overseas students receive the vaccination at least 2 weeks before they attend university (whenever possible) to ensure a full immune response.

2. Where students are not vaccinated before leaving for university they can register with a new GP Practice once they arrive and arrange to get the vaccine there as soon as possible, ideally in freshers' week to give maximum protection, and no later than 31 March 2016.

3. The freshers vaccination programme was introduced in 2014 as a time-limited programme that would run until 2017 when the 2013 cohort of S3 pupils will reach university age. Due to the introduction of the Men ACWY vaccine, and all 14-18 year olds being vaccinated over the course of this financial year, this will be the final year of the freshers programme.

4. From 2016/17 onwards the Men ACWY vaccine will only be given to S3 pupils by NHS Boards through schools.

Catch-up programme for 14-18 year olds

5. The Men ACWY catch-up programme for 14-18 year olds will commence from 1 August 2015.

6. It will be delivered in two phases over this financial year (2015/16). Phase one will run from 1 August – 31 March 2016 and be delivered by General Practices **only**. Phase two will run from 1 January – 31 March 2016 and will be delivered by **both** NHS Boards and General Practices.

Eligibility

Freshers Programme

7. Freshers should now be offered the Men ACWY vaccine in place of the Men C vaccine.

8. Eligible patients are those under 25 and attending university for the first time in Autumn 2015.

9. GP Practices will not be required to identify or contact eligible patients, with the emphasis being for first time university students under the age of 25 to request the vaccination.

Catch-up programme for 14-18 year olds

10. The JCVI has recommended the vaccination of all adolescents aged 14-18 years of age with Men ACWY vaccine as soon as possible. In order to deliver the catch up element of the programme, both NHS Boards and GP Practices will be involved.

11. From 1 August 2015 to 31 March 2016 GP Practices will be responsible for vaccinating the following cohorts of school leavers. To give maximum protection these cohorts should ideally be vaccinated before 31 October 2015 and no later than 31 March 2016:

- **18 year olds** vaccinate those born between **2 August 1996 28 February 1997**. This cohort are advised to contact their GP Practice to make arrangements to receive the vaccination.
- 17/18 year olds (2014/15 S6 cohort, DOB: 1 March 1997 28 February 1998) –
 vaccinate all S6s who leave school this summer (2015). In addition, vaccinate those
 who are of S6 age but who left school in previous years. A Scottish Government
 funded central letter will invite the patient to contact their GP practice to be vaccinated
- 16/17 year olds (2014/15 S5 cohort, DOB: 1 March 1998 28 February 1999) school leavers only - vaccinate S5s who leave school this summer (2015) and do not go into S6. In addition, vaccinate those who are of S5 age but who left school in previous years. A Scottish Government funded central letter will invite those who have left school to contact their GP practice to be vaccinated. Those who return to school will be vaccinated in school during the 2015/16 academic year.
- 15/16 year olds (2014/15 S4 cohort, DOB: 1 March 1999 29 February 2000) school leavers only - vaccinate S4s who leave school this summer (2015) and do not go into S5. This will be supported by a Scottish Government funded central letter as per paragraph 12 below.

12. From 1 January to 31 March 2016 GP Practices will be responsible for vaccinating the following cohorts:

 16/17 year olds (2015/16 S5 Christmas leavers (the 2014/15 S4s), DOB: 1 March 1999 – 29 February 2000) - vaccinate S5s who leave school at Christmas 2015. A Scottish Government funded central letter will invite those who have left school to contact their GP practice to be vaccinated. Those who return to school will be vaccinated in school during the 2015/16 academic year.

13. From 1 January to 31 March 2016 NHS Boards (in schools) will be responsible for vaccinating the following cohorts:

- 2015/16 S6s (2014/15 S5s)
- 2015/16 S5s (2014/15 S4s)
- 2015/16 S4s (2014/15 S3s)
- 2015/16 S3s routine cohort (2014/15 S2s)

CLINICAL GUIDANCE FOR HEALTHCARE PROFESSIONALS

Background to the introduction of Men ACWY vaccination

1. The Joint Committee on Vaccination and Immunisation (JCVI) met on 4 February 2015 to consider the most recent epidemiological evidence in relation to an increasing number of cases of Meningitis W (Men W) in the UK. The Committee advised that the replacement of Men C vaccine with Men ACWY vaccine for the adolescents and freshers' vaccination programmes was likely to be beneficial in controlling invasive Men W disease and against Men C. The JCVI recommended that the replacement should be implemented from academic year 15/16. The Committee also recommended that a catch-up programme for all 14 to 18 year olds using Men ACWY vaccine should also be offered as quickly as possible in order to generate direct protection against Men W for those vaccinated and indirect (herd) protection for the rest of the population, including infants.

Recommendations for the use of the Men ACWY vaccines (Nimenrix® and Menveo®)

Administration

2. Nimenrix[®] and Menveo[®] are given intramuscularly into the upper arm or anterolateral thigh. Full guidance on the administration is included in the relevant chapter of the Green Book.

Dosage

3. Individuals should be given a single dose of 0.5ml.

Contraindications

4. There are very few individuals who cannot receive meningococcal vaccines. When in doubt, appropriate advice should be sought from an immunisation co-ordinator rather than withhold immunisation.

- 5. The vaccines should not be given to those 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

6. Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given meningococcal vaccines in accordance with the routine schedule. These individuals may not make a full antibody response. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be needed.

Concomitant administration with other vaccines

7. Meningococcal vaccines can be given safely with other routine adolescent vaccines.

Consent

8. See Chapter Two of *Immunisation against infectious disease* ('the Green Book') <u>https://www.gov.uk/government/publications/consent-the-green-book-chapter-2</u>

Pharmacy Issues

Vaccine Brand Names and Manufacturer

9. Nimenrix® and Menveo® manufactured by GlaxoSmithKline.

Presentation

10. Menveo® is supplied as a powder in a vial and a 0.5ml solution in a pre-filled syringe. The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe (containing MenCWY solution) to the vial containing the powder (MenA).

11. Nimenrix® is supplied as a powder in a vial (MenACWY) and 0.5ml solvent in a prefilled syringe. The vaccine must be reconstituted by adding the entire contents of the prefilled syringe to the vial containing the powder.

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

Vaccine Supply

13. The Men ACWY vaccines should be ordered in the usual way from NHS board vaccine holding centres.

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

Vaccine Storage

15. 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. 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

16. NHS Board vaccine holding centres should ensure sufficient fridge space is available for the Men ACWY vaccine.

17. Each site holding vaccine is asked to review current stocks of all vaccines. A maximum of 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.

18. 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.

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

Reporting of Adverse Reactions

20. Suspected adverse reactions (ADR) to vaccines should be reported via the Yellow Card Scheme (<u>https://yellowcard.mhra.gov.uk/</u>). Chapter Nine of the Green Book gives

detailed guidance which ADRs to report and how to do so. Additionally, Chapter Eight of the Green Book provides detailed advice on managing ADRs following immunisation.

21. 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.

Surveillance

22. The programme will be carefully monitored by the Medicines and Healthcare products Regulatory Agency (MHRA).

Patient Group Direction (PGD)

The requirement for Patient Group Directions is described in HDL(2001)7 available 23. from http://www.sehd.scot.nhs.uk/mels/HDL2001 07.HTM of The use PGDs for administration of vaccines is described in detail in chapter 5 of the 'Immunistion against Infectious Disease' (The Green Book) available athttps://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147823/Gree n-Book-Chapter-5.pdf

24. A specimen Patient Group Direction (PGD) for administration of Menveo/Nimenrix has been developed by Health Protection Scotland. This is available at: <u>http://www.hps.scot.nhs.uk/immvax/pgd.aspx</u>.is

Health Information systems (CHSP-S and GP)

25. GP IT systems will be adapted to enable recording of Men ACWY vaccinations.

26. The Child Health Surveillance Programme for School (CHSP-S) system will be adapted to provide full & recall functionality for Men ACWY vaccination for pupils in S3 (and by way of catch-up for S4-S6 pupils) for the start of the Spring term 2016 and thereafter. This will replace existing Men C functionality.

Vaccine Uptake and Data Collection

27. The delivery of the Men ACWY programme spans both primary care and school health delivery mechanisms. As such there needs to be full exchange of data on Men ACWY vaccinations between primary care and school health teams to 1) reduce the risk of duplicate vaccination or missed vaccinations through uncertain vaccine histories and 2) accurately measure and analyse uptake data through CHSP-S. NHS Boards should ensure that adequate mechanisms exist for the sharing of data between school health and GPs. The minimum data to be shared between services should include CHI, name, gender, GP, and vaccine; name, product name, batch number, expiry date and data given.

Funding Arrangements

28. The Scottish Government will fund the additional vaccine costs associated with implementation of the Men ACWY vaccination programme. Due to the Men ACWY vaccine replacing the Men C vaccine used in the routine Men C vaccination programme in S3, the Scottish Government will look to recoup the existing spend on the Men C vaccine against the overall vaccines costs of the Men ACWY programme.

29. For the first year of the programme invoices for the Men ACWY vaccine will be paid directly by the Scottish Government. 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.

30. From year two of the programme onwards, NHS Boards will pay the vaccine invoices directly and like the childhood flu, rotavirus and shingles vaccination programmes, will be reimbursed by the Scottish Government, less the amount NHS Boards would have paid for the Men C vaccine used in the routine Men C vaccination programme.

Contractual Arrangements

31. We ask NHS Boards to ensure that practice attached staff are appropriately engaged in assisting practices to deliver vaccinations.

32. The existing Men C Freshers Vaccination DES has been updated to reflect that claims for payment can be made for the Men ACWY vaccination. This will be available on SHOW once published. (See http://www.show.scot.nhs.uk/publications/).

33. As previously notified the Scottish Government is meeting the majority of the vaccine purchase costs associated with the freshers programme and the catch up programme for adolescents. NHS Boards are meeting the delivery costs, including GP costs, from their baseline resources.

COMMUNICATIONS AND INFORMATION FOR PATIENTS, PARENTS AND HEALTH PROFESSIONALS

Communications

1. A central invitation letter and leaflet will be sent to all young people who were either S6 or S5 in the 2014-15 academic year, asking them to make an appointment with their GP if they have left school. A short social media campaign will commence from August 2015 to coincide with the delivery of these invitations, targeting anyone aged 16-18 years who has left school. Posters and leaflets will be distributed locally. Members of the public should be directed to <u>www.immunisationscotland.org.uk/menacwy</u> for up to date information.

2. Young people who will be vaccinated at school will receive an information pack from their school with a letter, leaflet and consent form.

3. The leaflet will be available in Polish, Chinese, Urdu and easy read format and can be found at: <u>http://www.immunisationscotland.org.uk/vaccines-and-diseases/menw.aspx</u>. NHS Health Scotland is happy to consider requests for other languages and formats. Please contact 0131 314 5300 or email <u>nhs.healthscotland-alternativeformats@nhs.net</u>.

Educational resources for registered healthcare professionals

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/healthprotection/immunisation/meningococcal-acwy-immunisation-programme-foradolescents.aspx