

## **VACCINE UPDATE**

Protecting and improving the nation's health

Issue 291, February 2019

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### **BOOK NOW AND SAVE THE DATES**



## National Immunisation Network Meeting 2019

**Tuesday 21 and Wednesday 22 May** 

Londor

The annual NIN conference now in its 7<sup>th</sup> year is an important highlight in the UK Immunisation calendar providing an opportunity to meet each other face to face and share knowledge and experience.

According to the World Health Organisation, vaccines, along with clean water, are the public health interventions that have had the greatest.

vaccines, along with clean water, are the public health interventions that have had the greatest impact on the world's health. This immunisation programme year has been exciting and busy with many new developments including the announcement of the HPV vaccine programme for boys.

The National Immunisation Network provides critical vaccine programme information regarding implementation, vaccine supply, training and related clinical matters. It is a mechanism for feedback on many issues and provides a regular clear channel for communication between all the screening and immunisation teams and stakeholders working across England in various health care settings.

Read on for details of how to attend.

### CONTENTS

Welcome to all of our new readers and thank-you for subscribing to Vaccine Update.

Shingles vaccine coverage report for those becoming 70 and 78 years of age in April to September 2018

Vaccine coverage estimates for the school based meningococcal ACWY (MenACWY) adolescent vaccination programme

Vaccine coverage estimates for the school based tetanus, diphtheria and polio (Td/IPV, 'school leaver booster') adolescent vaccination programme

Administration of rotavirus vaccine

New award scheme recognises flu vaccine uptake in care homes across the North

Health information study

The EU Falsified Medicines Directive (FMD) and Delegated Regulation as applicable to centrally supplied vaccines for the national immunisation programme

Further guidance on FMD and the Delegated Regulation

BCG vaccine (AJ Vaccines) for the national BCG programme – current stock expires 30 April 2019

Update on MMR vaccine ordering restriction

Reminder about vaccine ordering

Flu Vaccine information and availability 2018/19 for the children's national immunisation programme

Reporting any remaining unused Flu Vaccine ordered for the children's flu programme

### Welcome to all of our new readers and thank-you for subscribing to Vaccine Update. We would like to invite you to attend our immunisation conference in May.

This Public Health England (PHE) two-day meeting will focus on current and emerging scientific issues in immunisation and implementation issues relating to PHE's national immunisation programme.

The theme of the meeting is 'Vaccination: back to the future' celebrating the success of the historic vaccine programmes and looking forward to new and improved vaccines. During this meeting attendees will have the opportunity to hear from experts involved in the work of immunisation across a range of diseases and specialities. As well as presentations from world-class epidemiologists and experts in immunisation from the UK including professor David Salisbury, we look also forward to welcoming Noel Brewer, Professor of Health Behavior (weblink 1), from Professor of Health Behavior at the Gillings School of Global Public Health at the University of North Carolina..

By providing you with the science and rationale behind immunisation policy and decision-making, and by sharing your experience and the latest developments, you will feel better equipped in your roles in this important public health work. This is a great opportunity to hear up-to-date information and to network with colleagues from across the immunisation community.



Subscribe to Vaccine Update <u>here</u>. Order immunisation publications <u>here</u>. For vaccine ordering and supply enquiries, email: <u>vaccinesupply@phe.gov.uk</u>

# Shingles vaccine coverage report for those becoming 70 and 78 years of age in April to September 2018: England

This is the second quarterly shingles report of the fiscal year 2018/19 evaluating shingles vaccine coverage among adults who became 70 or 78 years old between 1 April 2018 and 30 September 2018, assessed at the end of December 2018. This includes



Adults who turned 70 or 78 from July 2018 to 30 September 2018 (quarter 2). Adults who turned 70 or 78 from 1 April to 30 June 2018 (quarter 1).

Results from this report are not directly comparable to figures from previous years, which were based on a different methodology and eligibility criteria.

Overall, vaccine coverage among adults turning 70 and 78 years old during quarters 1 and 2 (1 April 2018 to 30 September 2018) is 31.4% for both cohorts. Subsequent quarterly reports will include coverage for adults turning 70 and 78 years old in quarter 3 and quarter 4 of the 2018/19 fiscal year

Among those turning 70 and 78 years old during quarter 2 (from 1 July 2018 to 30 September 2018) vaccine coverage was 28.5% and 28.6% respectively. Coverage among adults eligible in quarter 2 is greater than coverage achieved at the same point in time during quarter 1. This may be due to the convenience of adults receiving both the shingles and influenza vaccines at the same time during quarter 2.

Among those who became eligible during quarter 1 (from 1 April 2018 to 30 June 2018) vaccine coverage was 34.2% coverage for both the 70 year old and the 78 year old cohorts, compared to 19.6% and 20.5% during quarter 1, respectively. Subsequent cmulative quarterly evaluations for these birth cohorts assessed at the end of March and June 2019 should show increasing coverage as vaccinations received later in their 70th/78th year are captured.

Cumulative coverage for the fiscal year was observed highest among 75 year olds and lowest among 71 and 79 year olds. Vaccine coverage for each earlier routine cohorts (aged 72 to 75 years) continues to increase year on year through opportunistic vaccination.

A large difference in coverage was observed between the 71 and 72 year olds and between 79 and 80 year olds. The difference was likely in part to be associated to the change in eligibility criteria as half of these cohorts would have already had their 70th/78th birthday by 1 April 2018 when sufficient supply of the vaccine became available and may not have been offered the vaccine routinely. Further quarterly assessments of coverage will be undertaken in March 2019 and June 2019.

# Vaccine coverage estimates for the school based meningococcal ACWY (MenACWY) adolescent vaccination programme in England, to 31 August 2018

This is the third report of the MenACWY school based immunisation programme and updates 2016/17 data reported in January 2018. The MenACWY vaccine is offered to teenagers ages 13-15, primarily through schools (Year 9 and 10).

In 2017/18 a total of 137 local authorities (LAs) offered the routine MenACWY vaccination in Year 9. MenACWY coverage in Year 9 students in those 137 LAs was 86.2%. A total of 150/152 (98.7%) LAs reported coverage for the routine MenACWY vaccination in Year 10 (combined Year 9 2016/17 and Year 10 2017/18). MenACWY coverage in Year 10 students in those LAs was 84.6%. Average vaccine coverage for the 2017/18 Year 9 and Year 10 cohorts was 85.4% and compared to 83.1% in 2016/17.

Although the overall reported vaccine coverage in Year 10 is high there is variation between LAs. Whilst these adolescents are still attending schools efforts should be made to catch-up missing cohorts and cohorts with low coverage.

Opportunities for vaccination in primary care and at university freshers' events are also important. All individuals remain eligible for the MenACWY vaccine until they are 25.

The full report and associated data tables can be found at weblink 3.



Subscribe to Vaccine Update <u>here</u>. Order immunisation publications <u>here</u>. For vaccine ordering and supply enquiries, email: <u>vaccinesupply@phe.gov.uk</u>

# Vaccine coverage estimates for the school based tetanus, diphtheria and polio (Td/IPV, 'school leaver booster') adolescent vaccination programme in England, to 31 August 2018

This is the third vaccine coverage report for the Td/IPV schools based immunisation programme in England and presents updated data for school year 10 and new data for school year 9 in 2017/18. The Td/IPV vaccine is offered to teenagers ages 13-15, primarily through schools (Year 9 and 10).

137/152 (90.1%) local authorities (LAs) offered the routine Td/IPV vaccination in Year 9 in 2017/18. Td/IPV coverage in Year 9 in 2017/18 in those 137 LAs was 85.5%. A total of 150/152 (98.7%) LAs reported coverage for Td/IPV in Year 10. Td/IPV coverage in Year 10 in 2017/18 in those LAs was 82.9%.



Average vaccine coverage for the 2017/18 Year 9 school delivered programme was 85.5% compared to 83.0% in 2016/17. It is encouraging that since 2016/17 11 LAs have moved to offering the routine school leaver booster in Year 9 in 2017/18 and further areas have indicated that they will do so in the next year, enabling the programme to gradually move to the recommended Year 9 delivery of Td/IPV nationally (weblink 4).

The full report and associated data tables can be found at weblink 5.

### Administration of rotavirus vaccine

Since the introduction in 2013 of a rotavirus vaccine for babies, there has been a marked decrease in the burden of infants seeing their GP or being admitted to hospital with acute gastroenteritis. There has also been a decrease in the number of older children, adults and older adults with acute gastroenteritis, suggesting community transmission is being interrupted through the success of the immunisation programme for infants.

Rotarix® vaccine is licensed from 6 weeks and routinely offered in the UK from 8 weeks of age and the second dose with the second dose given 4 weeks later (i.e. from 12 weeks of age) in order to provide infants with early protection against rotavirus infection. Rotarix® vaccine is not licensed beyond 24 weeks of age. Immunisers seeing babies presenting late for routine immunisation are reminded to check the age of the baby to ensure that the Rotarix vaccine is not administered beyond 24 weeks of age.



## New award scheme recognises flu vaccine uptake in care homes across the North

In a bid to drive up flu vaccination uptake rates in the independent sector in 2018/19, PHE North in partnership with NHS England North, have introduced an award scheme across Yorkshire and the Humber, the North East and the North West.

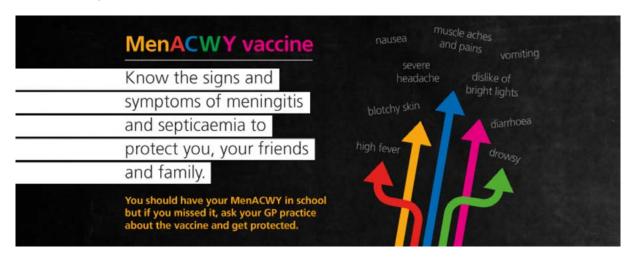
Efforts made by care homes (both residential and nursing), hospices and domiciliary care providers can be recognised through the scheme based on uptake achieved among health and social care staff directly involved in the care of vulnerable people. Those achieving 70% or above can receive gold accreditation, 60 - 69% silver accreditation and 50 - 59% bronze accreditation. The scheme will be evaluated in time for the 2019/20 season, when it's planned to continue. If you'd like to hear more about the scheme contact ann.burrows@phe.gov.uk.

### **Health information study**

When an individual who attends a university or other educational establishment is diagnosed with invasive meningococcal disease (usually meningitis or septicaemia), Public Health England's Health Protection Teams (HPTs) will request that information is distributed which promotes the awareness of symptoms and the importance of vaccination.

Currently the HPTs of London, the South East and South West are trialling a new digital health information pack which contains messages suitable for social media, emailing or for adding to a website. If appropriate, these HPTs will ask for information from this pack to be provided to a defined cohort of students and staff (for example the year group of the affected individual), request that an evaluation survey is circulated and discuss the possibility of holding a focus group to get feedback on the health information provided.

These messages and the evaluation surveys have been produced in collaboration with HPTs, national experts, meningitis charities and people who have been affected by the disease. Please contact the project group at healthinformationstudy@phe.gov.uk with any queries. For further information about prevention and management of meningococcal disease in higher education institutions please see weblink 6.



### Vaccine supply (centrally supplied)

# The EU Falsified Medicines Directive (FMD) and Delegated Regulation as applicable to centrally supplied vaccines for the national immunisation programme

**Since the 9 February 2019** there are legal obligations on the UK to prevent the entry of falsified medicinal products into the supply chain. The Delegated Regulation¹ of the Falsified Medicines Directive (FMD)² requires that prescription only medicines (POM) including vaccines entering the supply chain after this date carry safety features including an anti-tampering device (a seal) and a unique identifier (contained in a 2D barcode), and have their product data uploaded onto a central database. In addition, certain parts of the supply chain are required to perform authenticity checks, and at the end of the supply chain 'verify and decommission' products before they are supplied or administered to patients.

These changes affect all healthcare institutions pharmacies and other organisations across the UK who access centrally supplied products from PHE, except where the organisation is exempt (see information at the end of this article).

For the majority of PHE customers, in practice this means that at the end of the supply chain before a vaccine is administered to a patient, the integrity of the product seal should be checked and the barcode on the packaging should be scanned to **verify** authenticity and register the removal of the product from the supply chain on a central database **(decommission)**.

### Important points to note on PHE supplied vaccines

- Although the Regulation came into force on 9 February 2019, PHE will
  continue to issue products that are **not** subject to the requirements of FMD
  for a number of months. This is due to the large stockpiles of vaccines that
  are held by PHE, which were manufactured and delivered to PHE prior to the
  implementation date.
- Some products which were held by PHE prior to 9 February 2019 may display the safety features (barcode and seal), but not have data uploaded onto the database. These products are not subject to the requirements of FMD. The UK FMD Working group for Community Pharmacy has produced some guidance to help end users identify the types of packs that will need scanning for verification and authentication, and those that will not. Guidance and examples of "right" and "wrong" packs can be found at weblink 8.
- It is likely that PHE will be issuing a mixture of products that are subject/not subject to FMD to customers throughout mid-late 2019 and beyond, until all of the older packs are used. It is still permissible to administer older packs to patients.

<sup>1</sup> https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg\_2016\_161/reg\_2016\_161\_en.pdf 2 https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir 2011 62/dir 2011 62 en.pdf

### Further guidance on FMD and the Delegated Regulation

PHE has produced a guidance document to set out and clarify roles and responsibilities in the application of FMD and the Delegated Regulation to vaccines and other medicines centrally supplied by PHE to the NHS and other customers. This document is currently accessible via the ImmForm news page only, but will be uploaded to gov.uk in due course.

We would encourage all of our customers to visit the gov.uk page on FMD (weblink 7) and spend some time becoming familiar with the content and links to various other guidance documents on the implementation of the legislation. This page has recently been updated to include further information and guidance on:

- Error messaging and false alerts
- Falsified pack reporting
- Guidance for Wholesalers
- Guidance for parallel import license holders
- Homecare
- The Royal Pharmaceutical Society's professional guidance for pharmacists

NHS Digital toolkits for various types of healthcare provider to help them in the implementation of FMD can be found at weblink 7. Further information for NHS organisations on FMD can be requested by emailing fmd@nhs.net.

Questions about FMD and the safety features more broadly should be directed to fmd.safetyfeatures@mhra.gov.uk.

### Article 23

Organisations that are not considered to be healthcare institutions or pharmacies but who still supply medicines to the public are exempt from decommissioning vaccine under Article 23 of the Regulation. Article 23 allows wholesalers (i.e. Movianto, in the case of PHE vaccines) to decommission on behalf of these organisations.

The MHRA has published additional guidance on the use of Article 23 which can be found at weblink 9, along with additional information and guidance on FMD and the safety features. We would encourage our customers to review this guidance to determine whether the exemption provided by Article 23 applies to your organisation with respect to products ordered from PHE via ImmForm. If you believe that Article 23 applies to your organisation, you will need to contact helpdesk@immform.org.uk quoting your vaccine ordering account number, so that PHE can agree your assessment and ensure your account is set up correctly.

Organisations classed as Article 23 by ImmForm will receive decommissioned products and will only be required to check the anti-tampering device (seal) before a vaccine is administered to a patient.

# BCG vaccine (AJ Vaccines) for the national BCG programme – current stock expires 30 April 2019

The BCG vaccine currently being issued expires 30 April 2019. We will be issuing this stock until the end of March 2019, therefore please do not over order for your requirements. It is advised not to create locally held stockpiles.

The AJ Vaccines BCG vaccine has replaced the InterVax BCG vaccine for the national BCG programme. Please safely dispose of any remaining InterVax BCG product according to local protocols and in line with the guidance specified in Chapter 32 of the Green Book on Tuberculosis at weblink 10.

BCG vaccine supplied by AJ Vaccines is presented as a powder for reconstitution in a glass vial with synthetic stopper. Each pack ordered contains 10 vials, and will be accompanied by a pack of 10 vials of diluent. One vial of reconstituted vaccine contains 1 ml, corresponding to 10 doses (of 0.1 ml) for adults and children aged 12 months or over, or 20 doses (of 0.05 ml) for infants under 12 months of age.

### **Update on MMR vaccine ordering restriction**

There are currently two different vaccines available to order for the MMR programme, M-M-RvaxPro® and Priorix®. Orders for Priorix® are capped at 8 packs per order per week for accounts in England and Wales. Controls are also in place for Scottish customers. This is needed to rebalance central supplies.

The alternative MMR vaccine, M-M-RvaxPro®, remains available to order without restriction. If you specifically require additional Priorix® stock, for example because you serve communities that do not accept vaccines that contain porcine gelatine then please contact the ImmForm Helpdesk for assistance at helpdesk@immform.org.uk.

### Reminder about vaccine ordering

PHE maintains significant stockpiles of all our vaccines in support of the national immunisation programme.

Our usual ordering advice remains in place; that is do not create locally held stockpiles and order vaccines for the next 2 weeks only, as this avoids wastage from expiry and/or where there are local cold chain incidents. There is no requirement for any local stockpiling of PHE supplied products as that would adversely impact on PHE stock.

# Flu Vaccine information and availability 2018/19 for the children's national immunisation programme

PHE is now issuing the final batch of Fluenz Tetra® (KL2241B) for the 2018/19 season. This batch will continue to be issued until 14 March and expires on 1 April 2019.

### **Expiry dates for Fluenz Tetra®**

Batch numbers and associated expiry dates of Fluenz Tetra® for all batches that have been issued this season are set out in the table below. Expired batches are marked in red and should not be used.

Please ensure that the expiry date is always checked before use and that expired stock is disposed of in line with local policies and recorded through the ImmForm stock incident page.

Batch Number	Expiry Date
KJ2354	1 January 2019
KJ2356	2 January 2019
KJ2357	3 January 2019
KJ2355	4 January 2019
KJ2491	7 January 2019
KJ2502	10 January 2019
KJ2501	11 January 2019
KJ3272	21 January 2019
KJ3196	30 January 2019
KK2345	4 February 2019
KK2794	28 February 2019
KL2239	4 March 2019
KL2241	11 March 2019
KL2241B	1 April 2019

# Reporting any remaining unused Flu Vaccine ordered for the children's flu programme

As the vaccination period for flu draws to a close, it is important to remember that any vaccine that has expired, or remains otherwise unused at the end of the season, is recorded on ImmForm using the Stock Incident page.

This is to ensure that all stock is accounted for and supports efforts across the system to reduce the level of vaccine which may go unused at the end of the season. Please ensure that you select the appropriate reason (i.e. 'expired before use' or 'cold chain failure') when recording the disposal of any stock. If you are unsure how to record this information you can find help sheets on the ImmForm website. Alternatively, you can contact the helpdesk@immform.org.uk or 0844 376 0040 for assistance.

# Non-centrally supplied

### - for the non routine programmes

### **HEPATITIS A VACCINE**

### Adult

- **GSK:** Havrix Adult PFS singles and packs of 10 are available
- Sanofi Pasteur: Avaxim is currently available for orders without restrictions
- MSD: Very limited supplies of VAQTA Adult are available at the wholesaler AAH, but MSD is now out of stock. Replenishment is expected in April 2019

### **Paediatric**

- GSK: Havrix Paedatric PFS singles and packs of 10 are out of stock
- MSD: VAQTA Paediatric is available

### **HEPATITIS B VACCINE**

#### Adult

- **GSK**: Supplies of Engerix B PFS singles and packs of 10 are available
- GSK: Supplies of Engerix B vials singles and packs of 10 are available
- GSK: Supply of Fendrix is currently out of stock. Resupply is expected in March 2019
- MSD: HBVAXPRO 10 μg is out of stock until further notice
- **MSD**: HBVAXPRO 40 μg is out of stock until further notice
- The supplies of HBVAXPRO are expected to be restricted until further notice Please see statement at weblink 2

As hepatitis B renal vaccines (HBVAXPRO40 and Fendrix) are temporarily out of stock (with re-supply of Fendrix expected in March 2019), standard adult dose vaccine can be used if vaccination cannot be safely deferred. Renal dialysis patients should be routinely tested for hepatitis B immunity post vaccination as per national guidelines.

### **Paediatric**

- **GSK**: Engerix B Paediatric singles are available
- **MSD**: HBVAXPRO 5µg are available

### **COMBINED HEPATITIS A & B VACCINE**

- **GSK**: Twinrix Adult and Paediatric presentations are available
- GSK: Twinrix Adult packs of 10 are currently out of stock. Resupply is expected in May 2019
- **GSK:** Twinrix Paediatric is available
- GSK: Ambirix is available

### **COMBINED HEPATITIS A & TYPHOID VACCINE**

Sanofi Pasteur: Viatim is available to order without restrictions

### TYPHOID VACCINE

- **Sanofi Pasteur**: Typhim is available to order without restrictions
- PaxVax: Vivotif is available

### **RABIES VACCINE**

- GSK: Limited supplies of Rabipur are available. GSK is currently experiencing a supply delay due to manufacturing constraints through the first half of 2019
- **Sanofi Pasteur**: Rabies BP is currently out of stock. An alternative vaccine is available, please contact Sanofi Pasteur directly for more information

### PPV (PNEUMOCOCCAL POLYSACCHARIDE VACCINE)

- MSD: Limited stocks of Pneumococcal Polysaccharide Vaccine vials are currently available with next replenishment expected during March
- MSD: Limited stocks of PNEUMOVAX 23 PFS are currently available at our wholesaler AAH with next replenishment due in March
- Please see statement at weblink 2

### PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE

- Pfizer: Prevenar 13 is in stock
- GSK: Synflorix has now been discontinued from the UK market

### **VARICELLA ZOSTER VACCINE**

- GSK: Varilrix is currently available
- MSD: VARIVAX is currently available
- MSD: ZOSTAVAX stocks are currently available

### DIPHTHERIA, TETANUS AND POLIOMYELITIS (INACTIVATED) VACCINE

Sanofi Pasteur: Revaxis is available to order without restrictions

#### **MMR**

MSD: Limited stocks of MMRvaxPro are currently available for the private market

### **MENINGITIS ACWY VACCINE**

 GSK: Menveo is currently unavailable. Replenishment is expected in March 2019

Pfizer: Nimenrix is currently available

#### YELLOW FEVER

Sanofi Pasteur: Stamaril is available to order without restrictions

### **HUMAN PAPILLOMAVIRUS VACCINE**

MSD: Stocks of GARDASIL are available

MSD: Limited supplies of Gardasil 9 are available

### Web links weblink 1 https://sph.unc.edu/hb/health-behavior-home weblink 2 http://www.msd-uk.com/products/vaccines.xhtml weblink 3 https://www.gov.uk/government/publications/meningococcal-acwyimmunisation-programme-vaccine-coverage-estimates https://www.gov.uk/government/publications/routine-childhoodweblink 4 immunisation-schedule weblink 5 https://www.gov.uk/government/publications/school-leaver-boostertdipv-vaccine-coverage-estimates https://www.gov.uk/government/publications/meningitis-andweblink 6 septicaemia-prevention-and-management-in-higher-educationinstitutions weblink 7 https://www.gov.uk/guidance/implementing-the-falsified-medicinesdirective-safety-features weblink 8 https://fmdsource.co.uk/2018/11/22/right-and-wrong-scanningguidance-for-fmd-early-adopters/ weblink 9 https://assets.publishing.service.gov.uk/government/uploads/system/ uploads/attachment\_data/file/767788/Additional\_guidance on Article\_23\_HCI\_s\_and\_Article\_26.pdf https://www.gov.uk/government/publications/tuberculosis-the-greenweblink 10 book-chapter-32

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