

PCV CHRISTMAS SPECIAL

# **VACCINE UPDATE**

Protecting and improving the nation's health

Issue 303, December 2019

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### We are changing our vaccination schedule!

# Changes to the infant pneumococcal conjugate vaccine (PCV) schedule taking place in the New Year (2020)

For babies born from 1 January 2020, the vaccination schedule for the pneumococcal conjugate vaccine (PCV) is changing. On the advice of the Joint Committee on Vaccination and Immunisation (JCVI), infants will follow a 1 + 1 PCV schedule with a single priming dose of PCV offered with the other routine infant vaccinations at 12 weeks of age and a booster dose at one year of age (on or after the first birthday).

This schedule change means that instead of three injections at the 8 and 16 week appointments (and one at 12 weeks), babies will only receive two injections at each of these appointments, plus rotavirus by mouth at 8 and 12 weeks.

The impact to the schedule will come into effect in late February 2020 when babies born on or after 1 January 2020 will no longer require an 8 week PCV dose. The first PCV vaccines to be given on the new 1 + 1 schedule will start in late March 2020 when these infants are 12 weeks of age.

Please note however, that infants born on and before 31 December 2019 will remain on the previous 2 + 1 schedule (dose of PCV at 8 and 16 weeks, and a booster dose given at one year old).



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The EU FMD and Delegated Regulation as applicable to PHE supplied vaccines for the national immunisation programme England, Wales and Northern Ireland will change the PCV schedule from January. In Scotland, this will happen slightly later.

This change to the schedule is being made because the pneumococcal vaccine programme introduced in 2006 has been so successful. High uptake of the very effective pneumococcal conjugate vaccine has resulted in excellent control of the types of pneumococcal bacteria that the vaccine protects against. Very little disease caused by these bacteria is now seen in the UK and the JCVI have therefore agreed that a single dose of vaccine in infancy and a booster dose on or after the first birthday should continue to provide good protection for children and for the community as a whole.

### **Pneumococcal infection**

Pneumococcal disease is the term used to describe infections caused by the bacterium *Streptococcus pneumoniae* (also called pneumococcus).

*S. pneumoniae* is an encapsulated Gram-positive coccus. The capsule is the most important virulence factor of *S. pneumoniae*; pneumococci that lack the capsule are normally not virulent. Over 90 different capsular types have been characterised but prior to the routine conjugate vaccination programme, around 69% of invasive pneumococcal infections were caused by the ten most prevalent serotypes.

Some serotypes of the pneumococcus may be carried in the nasopharynx without symptoms, with disease occurring in a small proportion of infected individuals. Other serotypes are rarely identified in the nasopharynx but are associated with invasive disease. The incubation period for pneumococcal disease is not clearly defined but it may be as short as one to three days. The organism may spread locally into the sinuses or middle ear cavity, causing sinusitis or otitis media. It may

also affect the lungs to cause pneumonia or cause systemic (invasive) infections including bacteraemic

pneumonia, bacteraemia and meningitis.

Transmission is by aerosol, droplets or direct contact with respiratory secretions of someone carrying the organism and usually requires either frequent or prolonged close contact. There is a seasonal variation in pneumococcal disease, with peak levels in the winter months.

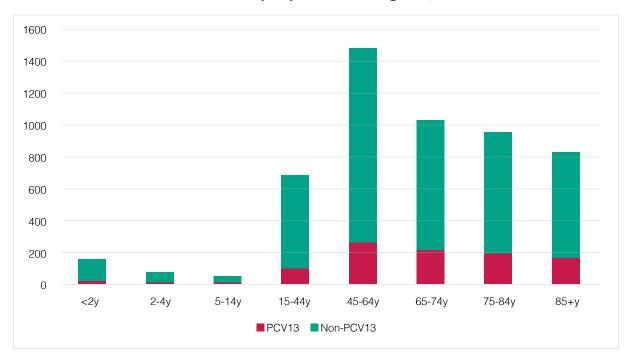
Invasive pneumococcal disease is a major cause of morbidity and mortality. It particularly affects the very young, the elderly, those with an absent or nonfunctioning spleen and those with other causes of impaired immunity. Recurrent infections may occur in association with skull defects, cerebrospinal fluid (CSF) leaks, cochlear implants or fractures of the skull.



### **Background to the PCV schedule changes**

The routine infant PCV programme was introduced in the UK in 2006, initially using a 7-valent vaccine (PCV7) which was replaced with the 13-valent vaccine (PCV13) in 2010. It has been highly successful, with large and sustained decreases in pneumococcal disease due to the 13 serotypes contained in the vaccine across the population and especially in young children. The PCV13 vaccine has proven to have very high effectiveness and there has been a high uptake of the vaccine for a number of years.

### Invasive Pneumococcal Disease (IPD) Cases in England, 2018 to 2019



- IPD incidence due to PCV13 serotypes has remained relatively stable since 2013 to 2014
- currently, only 19% of all IPD cases are due to PCV13 serotypes, nearly all among adults and older adults
- less than 5% of IPD cases were in children aged <5 years</li>

Given the success of the programme, both in those vaccinated, and in the wider population (through indirect population protection often referred to as 'herd immunity'), the JCVI reviewed the infant pneumococcal vaccination programme. They concluded that as the maximum direct and indirect benefit from the PCV13 programme has already been achieved, with very little carriage or disease due to the PCV13 serotypes, multiple doses of PCV13 should no longer be required in the childhood immunisation programme. Following detailed review and a stakeholder consultation, the JCVI agreed that a move from the 2+1 schedule to a 1+1 schedule was appropriate for the UK situation and that PCV13 should now be offered to infants at 12 weeks and at one year of age.<sup>1</sup>

<sup>1.</sup> Joint Committee on Vaccination and Immunisation. Minutes of the meeting on 06 June 2018. Available at: app.box.com/s/iddfb4ppwkmtjusir2tc/file/305779572165 www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#minutes

The 12-week dose will provide the infant with some protection against pneumococcal infection due to the vaccine serotypes and, importantly, will also prime their immune system to make a good response to the booster dose given at one year of age. The booster dose is particularly important, not only in providing individual protection, but also in preventing the vaccinated child from carrying pneumococcal bacteria in their nasopharynx and passing them on to others. This interruption of transmission is vital to sustaining the high levels of herd protection for unvaccinated susceptible individuals achieved to date in the UK.

The change in the UK pneumococcal recommendations has been carefully considered and is supported by several studies, including a clinical trial comparing the immunogenicity of the 2+1 and 1+1 schedules.<sup>2</sup> The 1+1 schedule should continue to provide individual protection and maintain population protection against pneumococcal disease. The epidemiology of pneumococcal disease will continue to be monitored very carefully and any changes in disease incidence in any age group can be detected, assessed and actioned quickly if needed.

If you want to find out more about how we monitor the epidemiology of *Streptococcus pneumoniae*, its identification and capsular typing and The Vaccine Preventable Bacteria Section (VPBS), see our Vaccine Update Bug Special at weblink 1.

The move to a 1+1 schedule provides the opportunity to reduce the number of vaccines administered at immunisation appointments and provides space in the vaccine schedule should any new vaccines need to be introduced in the future.

All resources and materials to support the PCV schedule change are available to order now.

2. Goldblatt D, Southern J, Andrews N et al. Pneumococcal conjugate vaccine 13 delivered as one primary and one booster dose (1 + 1) compared with two primary doses and a booster (2 + 1) in UK infants: a multicentre, parallel group randomised controlled trial. The Lancet Infectious Diseases, February 2018; 18(2): 171-179.

# Merry Christmas to our Vaccine Heroes

This has been a challenging year in so many ways, and it has been important to recognise and acknowledge the contributions that each part of the workforce make every day to the national vaccination programme. The gift of vaccination is one that we would like every eligible child and adult to have and every day together we are making progress towards this goal. Once again we have changed the schedule, to introduce HPV to boys in year 8 and, due to the success of the pneumococcal infant programme we are moving to PCV 1+1, at twelve weeks and twelve months. Tremendous progress has been made and each one of you have contributed to this progress, so you should be very proud.

We would also like to thank you all for reading Vaccine Update this year and contributing so many fantastic articles which have made this year our most successful yet. Whatever you do to celebrate this Christmas, we wish you a peaceful and restful break and look forward to working with and alongside you in 2020.

### **PCV** resources

# Changes to the infant pneumococcal conjugate vaccine schedule – information for health professionals

This document provides more information about the schedule change and gives specific information about inadvertent scheduling errors, incomplete vaccination and advice for infants vaccinated abroad.

A short training slideset detailing the schedule change is also available to view and download.

Find both the guidance document and a link to the slideset at weblink 5 and weblink 6.

### The Redbook is being updated too!

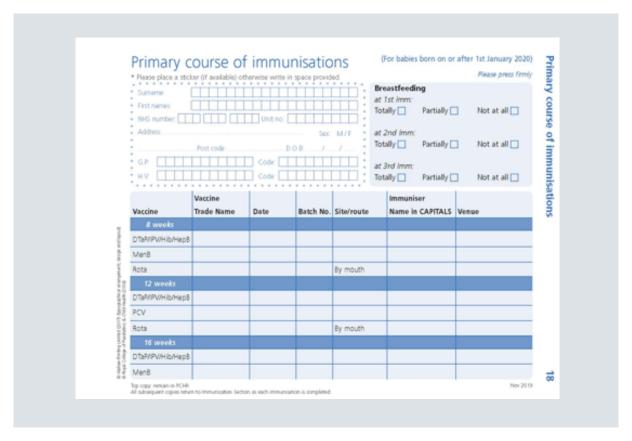
The Personal Child Health Record (PCHR) or 'Redbook' is given to parents and carers at their child's birth. It is the national standard health and development record and includes the immunisation schedules.

You can download a copy of the book at weblink 7 and it will soon include the three pages below:

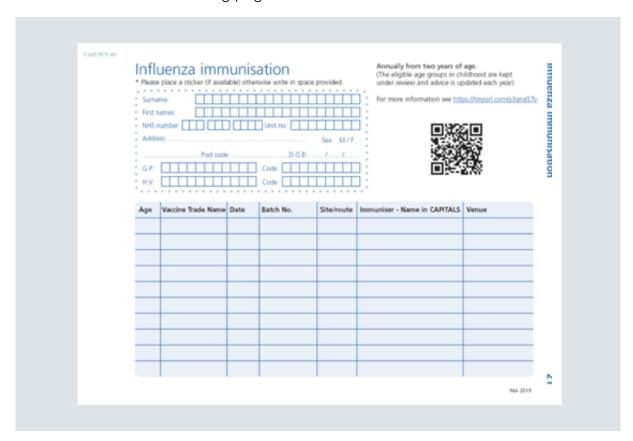
Pages 16 and 18 are the schedule pages and include the new PCV schedule.



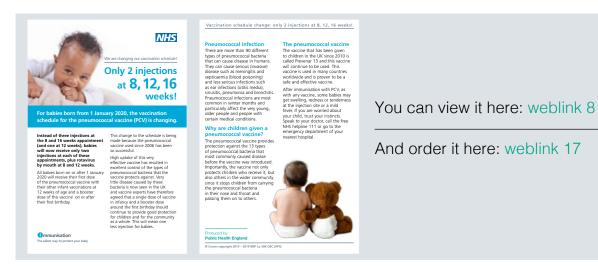
Age Due	will be offered the following vaccines (For babies born on or after 1st January 2020)		
8 weeks	DTaPriPV/Hib/HepB and MenB and Rota (diphtheria, tetanus, acellular pertussis (whooping cough), inactivated polio vaccine, Haemophilus influenzae b (Hib) vaccine, hepatitis B vaccine and meningococcal B vaccine and rotavirus vaccine)		
12 weeks	DTaP/IPV/Hib/HepB and PCV and Rota (diphtheria, tetanus, aceilular pertussis [whooping cough] inactivated polio vaccine, Haemophilus influenzae b [Hib] vaccine, hepatitis 8 vaccine, pneumococcal conjugate vaccine and rotavirus vaccine)		
16 weeks	DTaP/IPV/Hib/HepB and MenB (diphtheria, tetanus, acellular pertussis [whooping cough], inactivated polio vaccine, Haemophilus influenzae b [Hib] vaccine, hepatitis 8 vaccine and meningococcal 8 vaccine)		
One year	Hib/MenC (Haemophilus influenzae b [Hib] and meningococcal C vaccine) PCV (pneumococcal conjugate vaccine) MenB (meningococcal B vaccine) MMR (measles, mumps, rubella)		
Annually from 2 years old	Influenza Vaccine (The eligible age groups in childhood are kept under review and advice is updated each year)		
3 years 4 months	DTaP/IPV or dTaP/IPV (diphtheria or low dose diphtheria, tetanus, acellular pertussis, inactivated polio vaccine) PRE-SCHOOL INVIVIUNISATIONS MMR (measles, mumps, rubella vaccine)		
12 and 13 years (School year 8)	HPV (human papillomavirus vaccine) (two doses at least 6 months apart)		
Around 14 years (School years 9/10)	dT/IPV (low dose diphtheria, tetanus, inactivated polio vaccine) TEENAGE BOOSTER MenACWY (meningococcal ACWY vaccine)		
Some babies need BCG and/or extra hepatitis B vaccines. If in doubt discuss this with your midwife/health visitor.			
The immunisations your child is offered may change with time. Your health visitor or practice nurse will talk to you and give you written information about immunisations. This and other information is available on NHS UK			



It will also include the following page 81 which features the influenza schedule:



### PCV flyer for parents and healthcare professionals



**Complete routine schedule can be found here** weblink 9. The immunisation schedules have been updated to include the schedule change (two schedules going to be available until all children are on the same schedule)

Routine childhood schedule can be downloaded from weblink 10.

### Vaccination of individuals with uncertain or incomplete immunisation status.

This algorithm has been revised to include the PCV schedule change (weblink 11).

Title For babies born up to and including 31 December 2019	Product code	Product code	Title for babies born on or after 1 January 2020	Link
N/A		2019185P	PCV flyer – for parents and healthcare professionals – only 2 injections at 8, 12, 16 weeks	weblink 8
A guide to immunisations up to one year of age (born up to and including 31 December 2019)	3109328D	3109328P	A guide to immunisations up to one year of age (born on or after 1 January 2020)	weblink 12
Immunisations at one year of age (babies born up to and including 31 December 2019)	2902127C	2902127P	Immunisations at one year of age (babies born on or after 1 January 2020)	weblink 13
Childhood immunisations guide for the parents of premature babies (born up to and including 31 December 2019)	2019183A	2019183P	Childhood immunisations guide for the parents of premature babies (born on or after 1 January 2020)	weblink 14
Pre-school immunisations: guide to vaccinations for children aged 2 to 5 years (born up to and including 31 December 2019)	3197560D	3197560P	Pre-school immunisations: guide to vaccinations for children aged 2 to 5 years (born on or after 1 January 2020)	weblink 15
Immunisations for young people (autumn 2019 schedule)	2902598B	2902598P	Immunisations for young people (January 2020 schedule)	weblink 16

### Ordering your free resources from the Health Publications website

There are still consent forms going out to parents without the 'Protecting your child from flu' leaflet and HPV consent forms going out to school children without 'HPV your guide to the vaccination' leaflet. It is so important to include the leaflet as the integral part of the consent process. Please place your orders today. The new site is easy to use and with free delivery, it really is a gift (see weblink 17).



### Lab focus continues

Our previous editions focused on the wonderful work our bacteriologists and virologists do in support of the vaccine programmes and so we complete the year celebrating our vaccine lab heroes in the Enteric Virus Unit who work on rotavirus and polio eradication.

### The Enteric Virus Unit, Virus Reference Department, Colindale

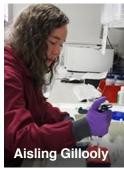
The Enteric Virus Unit is a small and dynamic team providing expertise and support for surveillance programmes and developmental work. We work very closely with colleagues within the Virus Reference Department and the Immunisation department. Our work covers outbreak investigation and characterisation of enteric viruses including norovirus, enterovirus, astrovirus, sapovirus and rotavirus.

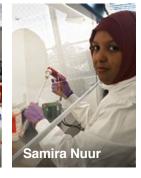
### **Rotavirus Characterisation**

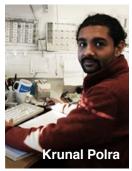
In 2013, the UK introduced the oral rotavirus vaccine into the infant immunisation programme to control the impact of rotavirus infection in children. As with other vaccine-preventable diseases, PHE initiated a national surveillance programme to assess not only the impact of the rotavirus vaccination in the community but also the effect on rotavirus diversity. The vaccine resulted in £12.5 million saving in RV-associated healthcare costs within a year of implementation highlighting the success of the immunisation programme.

The Unit performs tests on referred positive rotavirus samples submitted for specialist characterisation using a range of molecular methods. We produce characterisation results based on the molecular amplification of 2 different sections of the virus genome. We are also able to differentiate natural rotavirus from vaccine-associated infections. The analysis of the genetic characteristics of the circulating rotavirus at national level, allow us to monitor the effect of the vaccine on rotavirus diversity.











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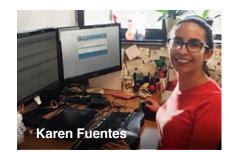
In 2018, the Enteric Virus Unit processed and typed over 1200 rotavirus positive samples. The Unit is also committed to the development and improvement of novel tools and technology in order to ensure an effective and strong surveillance programme.

### Poliovirus Eradication support – Enterovirus Typing

We also support the Poliovirus eradication effort and the Enterovirus surveillance programme working very closely with the Poliovirus Reference Service. We usually undertake characterisation of virus isolates produced by the Polio laboratory, of samples associated with more serious conditions like acute flaccid paralysis and of environmental samples.

### Improving vaccine uptake in the West Midlands

Hello, I'm Hayley Field, one of the Screening and WE DID Immunisation coordinators based in Birmingham. I have worked in public health for the past 11 years, the last six of these I have worked as part of the West Midlands team. Our team currently consists of 20 Public Health England staff members coming from a variety of working backgrounds. The Screening and Immunisation team supports NHS England in commissioning the immunisation programme



As a member of the Screening and Immunisation team it is my role to support NHS England colleagues with the local implementation and monitoring of vaccine programmes and offering expert public health advice to make the population healthier and reducing inequalities in health between different groups. We also provide assurance to our Local Authorities of the delivery of safe and effective services protecting the eligible population.



Our team have implemented many initiatives to increase uptake in immunisation programmes. Here are two examples:

### Children's Seasonal Influenza Reminder Letters for 2 and 3 year olds

Children's Seasonal Influenza Reminder Letters for 2 and 3 year olds, using the Child Health Information service to send letters to all children aged 2 and 3 years of age informing their parents of their eligibility for flu vaccine and advising them to contact their GP Practice to arrange an appointment. This has proven successful across our area raising uptake in the first year by an average of 5% in 2 year olds and 4% in 3 years old, maintaining the increased uptake in the following years. This will be the 3rd year this has been carried out for the whole area and will be continued for a further 2 years, when further evaluation will be carried out.

#### **GP Scheme**

We have also implemented a GP Scheme which is aimed at improving the uptake of childhood immunisations. This scheme contained multiple tasks from a self-assessment, review of processes, attendance at 3 meetings through the period of the scheme, sharing best practice and a 'Did Not Attend (DNA) follow up' protocol, where children who had DNA'd twice were followed up by the registered practice to find the reason for the missed appointment and to rebook another appointment. The DNA Protocol evaluated well with 40% of these children subsequently vaccinated.

My focus is on promoting, ensuring and improving the accuracy, flow, recording and reporting of immunisation information for each of our programmes. Recently I have applied this focus to review and redesign the Neonatal Hepatitis B Programme in the Birmingham, Solihull and Black Country area which resulted in the change of delivery model from an Acute and GP Practice setting to a mixed model of GP practices and domiciliary service that includes a failsafe process to follow up on delayed vaccination or testing. This model has ensured safe and highly effective

delivery of the programme across the area.

I have also overseen the merger of the Child Health Information Systems across the West Midlands area, bringing together 14 systems in to one across the area. We are setting up an automatic data transfer between GP Practices and CHIS to improve data accuracy and reduce duplication of records. So far, half our GP practices signed up to the process, and I continue to discuss and encourage remaining practices to sign up to the process.

One piece of advice I would share with other teams would be data quality is key, incorrect data and poor data flows can hinder any improvements that are trying to be made or mislead areas which require improvement. Therefore data should be considered in all areas of our work.

# **Events** – coming soon

## **National Immunisation Network conference 21-22 April 2020**

Join us at Imperial university, Kensington, London for our two day event. Guest speakers, details and bookings opening soon.

### Fundamentals of Immunisation – book your place now!

Dates of Event: 9 March 2020 - 10 March 2020

Last Booking Date for this Event: 5 March 2020

Venue:

UCL Great Ormond Street Institute of Child Health 30 Guilford Street, London WC1N 1EH

Course fee: £175

Book at weblink 18

Public Health England and the UCL Great Ormond Street Institute of Child Health are running a **Fundamentals of Immunisation** course. This annual, two-day intense theoretical course is designed for those new to a role in immunisation and is most suited to those who give or advise on a range of different vaccines.

The course comprises a series of lectures from national immunisation experts and will provide delegates with up-to-the-minute information on the range of topics included in PHE's 'Core Curriculum for Immunisation Training'.

A basic level of prior immunisation knowledge and familiarity with the Green Book (Immunisation against infectious disease) will be assumed.

The programme includes the following topics:

- why immunisation matters
- the scientific basis of national vaccine policy: designing, informing and monitoring immunisation programmes – who does what?
- immunology of immunisation
- vaccine manufacture; vaccine trials; assuring the safety and quality of vaccines

- monitoring vaccine safety
- current issues in vaccine preventable diseases
- vaccine coverage data collections
- maximising immunisation uptake
- talking with parents about immunisation
- legal issues including consent
- practical issues: storage and administration

If you have any further queries, please do not hesitate to contact Leila Blackford, on +44 (0)20 7905 2107 or ich.paediatrics@ucl.ac.uk



# Vaccine Supply – centrally supplied

Centrally supplied vaccines can be used for the purposes defined in chapter 3 of the Green Book, and in the 'Vaccines available on ImmForm' helpsheet.

### Children's flu vaccine for 2019 to 2020

As in previous years, PHE is centrally supplying the following flu vaccines for children included in this year's flu programme, including those aged from six months to less than 18 years old in clinical risk groups. Please refer to the ImmForm website for the most up to date information on ordering for both vaccines.

Vaccine	Manufacturer	
Fluenz Tetra®	AstraZeneca	
Quadrivalent Influenza Vaccine (split virion, inactivated) (QIVe)	Sanofi Pasteur	

It remains the responsibility of GPs and other providers to order sufficient flu vaccine directly from manufacturers for older eligible patients of the flu programme in 2019 to 2020. Please refer to guidance from your respective health departments for arrangements in Scotland, Wales and Northern Ireland.

# **Expiry dates for Fluenz Tetra issued for the 2019 to 2020 children's programme**

The first batch of Fluenz Tetra® which was distributed this season, will expire on **8 January 2020**. Batch numbers and associated expiry dates for this and all other batches that will be issued this season are set out in the table below. Please ensure that the expiry date is always checked before use and that expired stock is disposed of in line with local policies. Any disposed stock should be recorded through the ImmForm stock incident page (weblink 19).

Batch	Expiry date in 2020	Batch	Expiry date in 2020
LJ2149	08-Jan	LJ2168	09-Jan
LJ2169	10-Jan	LJ2334	16-Jan
LJ2515	27-Jan	LK2526	06-Feb
LK2527	10-Feb	LK2979	13-Feb
LK2980	20-Feb	LK2981	27-Feb
LK2982	02-Mar	LL2196	05-Mar
LL2197	12-Mar	LL2198	16-Mar
LL2199	20-Mar	LL2567	26-Mar
LM3089	31-Mar	LL2570	01-Apr
LN2084	06-Apr		

### All influenza vaccines for the 2019 to 2020 season

Information on all influenza vaccines that have been marketed in the UK for the 2019 to 2020 season are available here weblink 20. Please refer to the flu letter for information on which vaccines are eligible for reimbursement in the 2019 to 2020 season (weblink 21).

### Christmas and New Year deliveries warning notice

All customers

Due to the Christmas and New Year Bank Holidays, there will not be any deliveries or order processing by Movianto UK on Wednesday 25, Thursday 26 December 2019 or Wednesday 1 January 2020. Order cut-offs will be earlier for some customers with delivery days falling after the bank holidays, to allow sufficient time for order processing. Please see the table below for revised order cut-off and delivery dates.

Customers with a standard delivery day of **Wednesday** should be aware that after **Wednesday 18 December 2019**, the next available delivery day will be **Wednesday 8 January 2020**.

Customers are reminded to be prepared for the break in deliveries and to order accordingly. Please make sure you have sufficient room in your fridge for any additional vaccine you wish to stock over this holiday period. Out of Schedule deliveries cannot be arranged for failure to place orders in good time.

Usual order cut-off day (by 11.55am)	Christmas/new year period order cut-off dates (by 11.55 am; revisions are in bold)	Delivery date
Friday	Friday 20 December	Tuesday 24 December
	No deliveries Wednesday 25 December 2019	
	No deliveries Thursday 26 December 2019	
Wednesday	Monday 23 December	Friday 27 December
Thursday	Tuesday 24 December	Monday 30 December
Friday	Friday 27 December	Tuesday 31 December
	No deliveries Wednesday 1 January 2020	
Tuesday	Monday 30 December	Thursday 2 January*
Wednesday	Tuesday 31 December	Friday 3 January
Thursday	Thursday 2 January	Monday 6 January
Friday	Friday 3 January	Tuesday 7 January
Monday	Monday 6 January	Wednesday 8 January

<sup>\*</sup>Customers in Scotland will receive this delivery on Wednesday 3 January 2020.

# Maternal Pertussis programme – Upcoming changes to dTaP/IPV vaccine

The maternal pertussis immunisation programme commenced in October 2012, initially using Repevax® vaccine (dTaP/IPV). From July 2014, Boostrix®-IPV (dTaP/IPV) has been supplied.

In January 2020, Repevax® will become available to order through ImmForm for use in the maternal pertussis immunisation programme instead of Boostrix®-IPV. This is a temporary change and it is anticipated that supplies will revert back to Boostrix®-IPV in autumn 2020.

This change is necessary as PHE is running down all stock of Repevax® before the introduction of Boostrix®-IPV across both the maternal pertussis and the pre-school booster programmes.

There is no other change to the maternal pertussis immunisation programme, further details about this programme can be found in chapter 24 of the Green Book: weblink 22

# Childhood pneumococcal programme – Upcoming changes to the PCV13 dosage schedule

With reference to the schedule change for PCV13 (Prevenar13) weblink 23, please ensure that you keep the change in schedule in mind when ordering Prevenar13 from ImmForm in the New Year and do not order too much. We recommend that customers hold a maximum of 2-4 weeks stock to minimise the potential for wastage.

# Ordering additional Gardasil for the universal HPV immunisation programme

Since 1 September 2019, the human papillomavirus (HPV) vaccine has been offered to boys, in addition to girls, as part of the routine school aged immunisation schedule. Customers can order the additional required volumes of Gardasil through ImmForm alongside vaccine used for the girls' programme.

### **Update to Bexsero Patient Information Leaflet**

Every pack of Bexsero (Meningitis B vaccine; 10 doses) is supplied with a pad of ten Patient Information Leaflets (PILs), as well as there being a single PIL inside each Bexsero pack. Since late-September 2019, an updated version of the PIL pad has been distributed with Bexsero orders.

Please dispose of the single PIL from inside the pack, as it will be out-of-date. We will advise further when the PIL supplied in the pack is in line with the PIL pad.

### MMR vaccine ordering

There are currently two different vaccines available to order for the MMR programme, MMRvaxPRO® and Priorix®. Orders for Priorix® are capped at 20 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, MMRvaxPRO®, 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 or 0844 376 0040.

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

Full information on FMD as it applies to centrally supplied vaccines for the National Immunisation Programme can be found in the April 2019 edition of Vaccine update (weblink 24).

ImmForm vaccines in FMD-compliant packs (i.e. subject to the requirements of the Delegated Regulation) are being distributed for the majority of centrally-supplied products. The last products to be issued in FMD-compliant packs will go live towards the end of 2019 and into 2020. The exact start dates will be different for different products (the month is indicated in the table below for each product).

We will continue to update this information as forecasts become more accurate so please check for updates via the ImmForm news pages (weblink 25) regularly. We would encourage all of our customers to visit the GOV.UK page on FMD (weblink 26) and spend some time becoming familiar with the content and links to various other guidance documents on the implementation of the legislation.



Subscribe to Vaccine update <u>here</u>. Order immunisation publications <u>here</u>. For centrally-supplied vaccine enquiries, email: <u>vaccinesupply@phe.gov.uk</u>

Product	Brand name	Month FMD-compliant packs will be issued which require verification and decommissioning
Pneumococcal conjugate vaccine (PCV)	Prevenar13	Live
DTaP/IPV vaccine for pregnant women	Boostrix-IPV	Live
Meningococcal Group ACWY vaccine	Nimenrix	Live
Measles-Mumps-Rubella (MMR) vaccine	MMR VaxPRO	Live
DTaP/IPV/Hib/HepB vaccine	Infanrix Hexa	Live
Tuberculosis vaccine (BCG)	BCG Vaccine AJV	Live
Meningococcal Group B vaccine	Bexsero	Live
Shingles (Herpes zoster) vaccine	Zostavax	Live
Hib/MenC vaccine	Menitorix	Live
Measles-Mumps-Rubella (MMR) vaccine	Priorix	Live
Rotavirus vaccine	Rotarix	Live
Human papillomavirus (HPV) vaccine	Gardasil	Live
DTaP/IPV vaccine for infants	Repevax	Live
Td/IPV vaccine	Revaxis	January 2020
Purified protein derivative (Mantoux test)	Tuberculin PPD-2TU	All stock will be in non-FMD packs (as it is unlicensed in UK)

PHE have also issued, and continue to issue, many products in FMD-barcoded packs that were manufactured before the legislation came into force. These packs are not required to be verified and decommissioned, but this can be done optionally.

Please note that the barcode on Rotarix batch AROLC284AA (exp. 31/05/2021) is non-serialised and therefore cannot be verified or decommissioned.

If you have identified yourself to PHE as being exempt from decommissioning under Article 23 of the Delegated Regulation and this has been agreed, then you will be supplied with decommissioned vaccine.

Please see our guidance for more information on the roles and responsibilities in relation to FMD and the Delegated Regulation, regarding vaccines and other medicines centrally supplied by PHE to the NHS and other customers. This document is accessible via GOV.UK (weblink 27).

# Vaccine supply non-routine programme

#### **HEPATITIS A VACCINE**

#### Adult

 GSK: Havrix Adult PFS singles are currently unavailable, resupply is expected in the middle of December 2019

• **GSK:** Havrix Adult PFS packs of 10 are available

Sanofi Pasteur: Avaxim is available
 MSD: VAQTA Adult is available

#### **Paediatric**

 GSK: Havrix Paedatric PFS singles are currently unavailable Resupply affected early February 2020

GSK: Havrix Paedatric PFS packs of 10 are available

• MSD: VAQTA Paediatric is available

#### **HEPATITIS B VACCINE**

### Adult

• GSK: Engerix B PFS singles and packs of 10 are available

• **GSK:** Engerix B vials singles are available

• **GSK:** Engerix B vials packs of 10 are unavailable

GSK: Fendrix is available

• MSD: HBVAXPRO 10 μg is unavailable until further notice

MSD: HBVAXPRO 40 μg is unavailable until further notice

### **Paediatric**

GSK: Engerix B Paediatric singles are available

MSD: HBVAXPRO 5µg are available

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

GSK: Twinrix Adult singles and packs of 10 are available

GSK: Twinrix Paediatric is available

GSK: Ambirix is available

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

• Sanofi Pasteur: Viatim is available

#### **TYPHOID VACCINE**

Sanofi Pasteur: Typhim is available

PaxVax: Vivotif is available



#### **RABIES VACCINE**

• **GSK:** Limited supply of Rabipur is currently available. Supply issues resulting from manufacturing constraints have now resolved, however, GSK do not expect the situation to fully normalise until late 2019

 Sanofi Pasteur: Rabies BP is currently out of stock. An alternative vaccine is available, please contact Sanofi Pasteur directly for more information

### PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPV)

- MSD: Limited supplies of Pneumococcal Polysaccharide Vaccine vials are available. (Please see page 12 of the Bug Special Vaccine Update. Issue 300, October 2019 for further information)
- MSD: Supplies of PNEUMOVAX 23 PFS are currently unavailable. Resupply is expected in April 2020

### PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (PCV)

Pfizer: Prevenar 13 is available

### **VARICELLA ZOSTER VACCINE**

- GSK: VARILRIX is currently available
- MSD: VARIVAX is currently available
- **MSD:** Supplies of ZOSTAVAX is currently unavailable. Resupply is expected Q1 2020

## DIPHTHERIA, TETANUS AND POLIOMYELITIS (inactivated)

VACCINE Sanofi Pasteur: Revaxis is available

# DIPHTHERIA, TETANUS, PERTUSSIS (acellular) AND POLIOMYELITIS (inactivated) VACCINE

GSK: Limited supply of Boostrix-IPV is currently available

#### **MMR**

MSD: Limited supply of MMRvaxPro is currently available

**GSK:** Limited supply of Priorix is currently available

#### **MENINGITIS ACWY VACCINE**

• **GSK:** Supply of Menveo is available

Pfizer: Nimenrix is currently available

#### YELLOW FEVER

Sanofi Pasteur: Stamaril is available

### **HUMAN PAPILLOMAVIRUS VACCINE**

MSD: Limited supply of GARDASIL is available

• MSD: Gardasil 9 is currently available

• **GSK:** Cervarix is currently available





### **Weblinks**

Weblink 1	www.gov.uk/government/publications/vaccine-update-issue-300-october-2019-bug-special-edition
weblink 2	www.gov.uk/government/publications/pneumococcal-the- green-book-chapter-25
weblink 3	www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7
weblink 4	www.gov.uk/government/publications/immunisation-schedule-the-green-book-chapter-11
weblink 5	https://publichealthengland-immunisati.app.box.com/s/wkwregsb204bawfmfj2n7ucugs8cg3o9
weblink 6	www.gov.uk/government/publications/pneumococcal- vaccination-guidance-for-health-professionals
weblink 7	www.rcpch.ac.uk/resources/personal-child-health-record-pchr
weblink 8	www.gov.uk/government/publications/pneumococcal- vaccination-for-infants-leaflets
weblink 9	www.gov.uk/government/publications/the-complete-routine-immunisation-schedule
weblink 10	www.gov.uk/government/publications/routine-childhood-immunisation-schedule
weblink 11	www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status
weblink 12	www.gov.uk/government/publications/a-guide-to- immunisations-for-babies-up-to-13-months-of-age
weblink 13	www.gov.uk/government/publications/immunisations-between-12-and-13-months-of-age
weblink 14	www.gov.uk/government/publications/a-quick-guide-to-childhood-immunisation-for-the-parents-of-premature-babies
weblink 15	www.gov.uk/government/publications/pre-school-vaccinations-a-guide-to-vaccinations-from-2-to-5-years
weblink 16	www.gov.uk/government/publications/immunisations-for- young-people
weblink 17	www.healthpublications.gov.uk/Home.html

weblink 18	https://onlinestore.ucl.ac.uk/conferences-and-events/faculty-of-population-health-sciences-c09/ucl-great-ormond-street-institute-of-child-health-d13/d13-fundamentals-of-immunisation-2020
weblink 19	https://portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2fVaccineSupply%2fVaccineSupply%2fStock-Incident%2fAdd-Stock-incident.aspx
weblink 20	www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content
weblink 21	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/788903/Annual_national_flu_programme_2019_to_2020pdf
weblink 22	www.gov.uk/government/publications/pertussis-the-green-book-chapter-24
Weblink 23	www.gov.uk/government/publications/vaccine-update-issue-302-november-2019-virus-special-edition
weblink 24	www.gov.uk/government/publications/vaccine-update-issue-293-april-2019
weblink 25	https://portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2fVaccineSupply%2fNews.aspx
weblink 26	www.gov.uk/government/publications/fmd-guidance-for-recipients-of-phe-supplied-vaccines
weblink 27	www.gov.uk/government/publications/fmd-guidance-for-recipients-of-phe-supplied-vaccines



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