



## Training and education

Public Health England and UCL Great Ormond Street Institute of Child Health are running a 'Fundamentals of Immunisation' course in March 2019. This annually held, 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 'National Minimum Standards and 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.

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### Fundamentals of Immunisation

**UCL Great Ormond Street Institute of Child Health**  
**30 Guilford Street, London WC1N 1EH**  
**11 and 12 March 2019**

Course fee: £150  
Places still available  
– book today to avoid disappointment  
([weblink 1](#)).



# Vaccine supply (centrally supplied)

## The Falsified Medicines Directive (FMD) as it applies to centrally supplied vaccines for the national immunisation programme

### What is FMD?

From 9 February 2019 there will be legal obligations on the UK to prevent the entry of falsified medicinal products into the supply chain. The Delegated Regulation<sup>1</sup> of the Falsified Medicines Directive (FMD)<sup>2</sup> 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 will be 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.

### Who does this affect?

These changes will affect all healthcare institutions (including General Practice), pharmacies and other organisations across the UK who access centrally supplied products from PHE, except where the person or institution is captured under Article 23 (see next page).

### How does this affect me?

For the majority of our customers (in particular GPs), 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).

NHS Digital are developing toolkits for various types of healthcare provider to help them in the implementation of FMD. Please visit the gov.uk page on FMD at [weblink 2](#) to access these and other guidance documents on the implementation of FMD.

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1 [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg\\_2016\\_161/reg\\_2016\\_161\\_en.pdf](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](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf)

### **Article 23**

Persons or institutions 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 2](#), 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 in your situation with respect to products ordered from PHE via ImmForm. If you believe that Article 23 applies, you will need to confirm this to [helpdesk@immform.org.uk](mailto:helpdesk@immform.org.uk) quoting your account number so that PHE can ensure your ImmForm account is set up correctly.

Customers 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.

### **Further points to note on PHE supplied vaccines and FMD**

Although the Regulation comes 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 beyond 9 February. This is due to the large stockpiles of vaccines that are held by PHE, which will have been 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.

It is likely that PHE will be issuing a mixture of products that are subject/not subject to FMD to customers from late Spring, until all of the older packs are used.

Further information and a wide range of guidance related to the implementation of FMD and the safety features for all stakeholders is available at [weblink 2](#). Specific guidance from PHE on centrally supplied vaccines and the implications of FMD will be included at this link in due course.

Any questions about FMD and the safety features more broadly should be directed to [fmd.safetyfeatures@mhra.gov.uk](mailto:fmd.safetyfeatures@mhra.gov.uk).

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

### 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. Several batches which have been distributed this season have now expired. These are marked in red and should, therefore, 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

### 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 at [helpdesk@immform.org.uk](mailto:helpdesk@immform.org.uk) or 0844 376 0040 for assistance.

### **Order controls for Fluenz Tetra®**

General Practices are able to order 2 packs (20 doses) per week (one order per week) and school providers can order up to 300 packs (3000 doses) per week. Changes to these order controls may be made at any time to respond to the programme needs. Any changes will be communicated via the news item on the ImmForm front page.

Please refer to guidance from your respective health departments for arrangements in Scotland, Wales and Northern Ireland.

### **BCG vaccine (AJ Vaccines) for the national BCG programme**

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.

Please note that the stock currently being issued expires on 30 April 2019, therefore please do not over order for your requirements. It is advised not to create locally held stockpiles.

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](mailto:helpdesk@immform.org.uk) or 0844 376 0040.

# 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:** Limited supplies of VAQTA Adult are available at the wholesaler AAH, but MSD is now out of stock. Replenishment is expected in February

#### Paediatric

- **GSK:** Limited supplies of Havrix Paediatric PFS singles and packs of 10 are available. Resupply is expected in May 2019
- **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:** Fendrix is available
- **MSD:** HBVAXPRO 10 µg is out of stock. Replenishment is not expected until 2020
- **MSD:** HBVAXPRO 40µg is out of stock

#### 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:** Ambirix is available

### COMBINED HEPATITIS A & TYPHOID VACCINE

- **Sanofi Pasteur:** Viatim is available to order without any 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 with replenishment expected late February
- **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 supply of Pneumococcal Polysaccharide Vaccine vials is currently available
- **MSD:** Limited supply of PNEUMOVAX 23 pre- filled syringes is currently available at wholesaler AAH

### PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE

- **Pfizer:** Prevenar 13 is in stock and available for the private market
- **GSK:** Synflorix will be discontinued in the UK market by February 2019

### VARICELLA ZOSTER VACCINE

- **GSK:** Varilrix is currently available
- **MSD:** VARIVAX is currently available
- **MSD:** ZOSTAVAX stocks are currently available for the private market

### 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 until mid- 2019
- **Pfizer:** Nimenrix is currently available for private sales

### YELLOW FEVER

- **Sanofi Pasteur:** Stamaril is available to order without restrictions

### HUMAN PAPILLOMAVIRUS VACCINE

- **MSD:** Stocks of GARDASIL are available for private market sales
- **MSD:** Limited supplies of Gardasil 9 are available

## Weblinks

Weblink 1     <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-2019>

Weblink 2     <https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features>