

# SCOTTISH EXECUTIVE

# Health Department

Dear Colleague

### NEW VACCINATIONS FOR THE CHILDHOOD IMMUNISATION PROGRAMME

This letter provides important information about forthcoming changes to the vaccines provided for the routine childhood immunisation programme in Scotland. Similar changes are being made in other parts of the UK. These changes are being made following the recommendation of the Joint Committee on Vaccination and Immunisation (JCVI).

- Change from live oral polio vaccine (OPV) to inactivated polio vaccine (IPV) The risk of polio infection being brought into the UK is now very low. This is because polio has been eliminated from large parts of the world due to the success of the global vaccination programme. JCVI has recommended that a switch can be made from live oral polio vaccine (OPV), which provides good community protection, to inactivated polio vaccine (IPV), which provides effective individual protection. Also, IPV does not carry any risk of causing vaccine associated paralytic polio, that occurred very rarely with OPV.
- Change from whole cell pertussis vaccine (wP) to acellular pertussis vaccine (aP) Acellular pertussis vaccines tend to cause less adverse reactions than whole cell pertussis vaccines, particularly at the injection site. JCVI has previously recommended that acellular pertussis vaccines are used in the routine childhood immunisation programme when acellular preparations become available that offer at least the same level of protection as the whole cell pertussis vaccine that is currently used. Products containing a five-component acellular pertussis vaccine which meet the JCVI recommendation are now available.

From the Chief Medical Officer, Chief Nursing Officer and Chief Pharmaceutical Officer

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#### For action

Chief Executives NHS Boards General Practitioners Practice Nurses Health Visitors Community Pharmacists Chief Pharmacists Immunisation Co-ordinators CPHMs Directors of Public Health Medical Directors NHS Boards Scottish Prison Service

#### For information

Directors of Nursing NHS Boards Specialists in Pharmaceutical Public Health Infectious Disease Consultants Consultant Paediatricians Consultant Physicians Clinical Director, SCIEH Chief Executive NHS Health Scotland NHS24

#### **Further enquiries**

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In line with these recommendations, from 27 September, the following changes will be made:

**Primary Immunisation** - DTaP/IPV/Hib (diphtheria, tetanus, five component acellular pertussis, inactivated polio and *haemophilius influenzae* type b vaccine) (brandname: Pediacel) will be supplied for primary immunisation. It replaces the DTwP-Hib and OPV vaccines that are currently given.

**Pre-school Boosting** - dTaP/IPV (low dose diphtheria, tetanus, five component acellular pertussis and inactivated polio vaccine) (brandname: Repevax) will be supplied for pre-school boosting. It replaces the DTaP and OPV vaccines that are currently given.

**Teenage Boosting** - Td/IPV (low dose diphtheria, tetanus and inactivated polio vaccine) (brandname: Revaxis) will be supplied for teenage boosting. It replaces the Td and OPV vaccines that are currently given.

These new vaccines should be used from the date they are received. We recommend that existing stocks of the vaccines being replaced are not used.

The first supplies of Pediacel, Repevax and Revaxis will be supplied by Vaccine Holding Centres from week commencing 27 September and orders should be placed in the usual way. GP surgeries will receive stocks of the new vaccines by 11 October. Further supplies will need to be ordered from Vaccine Holding Centres in the usual way.

Syringes and needles need to be ordered in advance from the usual source to administer Pediacel because this vaccine is supplied in a single-dose vial presentation.

Please note that the new vaccines provide protection against the same diseases as the vaccines supplied previously. The new vaccines are also given to children at the same ages as the previous vaccines, and an immunisation course started with the previous vaccines can and should be completed with the new vaccine.

Information resources for parents and health professionals are being sent from NHS Health Scotland to GP surgeries, Health Promotion Units, pharmacies, NHS24 and Immunisation Co-ordinators by the first week of September. The information resources have been carefully tested with parents and health professionals in the UK and will be available from 25 August on the new NHS Health Scotland website, www.healthscotland.com/immunisation.

Detailed guidance on these new vaccines, including updated advice on contraindications and adverse events, can be found in the revised Green Book chapters which will be supplied by NHS Health Scotland with the information materials and these chapters can be accessed from the Health Scotland website (<u>www.healthscotland.com/immunisation</u>). You are strongly recommended to read this advice since there are a number of changes.

The Summary or Product Characteristics (SPC) for each vaccine also provides detailed information about the vaccines.

Please note that while great progress has been made in global polio eradication, vigilance is still needed as cases of polio still occur in India, Pakistan, Nigeria and the surrounding countries. If there is any doubt about the vaccination status of children coming to the UK from these countries, or travelling to these countries, then they should be immunised. Guidance on immunisation of individuals with unknown or incomplete immunisation can be found in the revised Green Book chapters and these chapters can be accessed through the Health Scotland website (www.healthscotland.com/immunisation). Further details of the changes to the vaccines supplied are attached in the Annex. If you have enquiries please discuss with local Immunisation Co-ordinators.

We hope these new resources together with the new vaccines, will help you in implementing the changes to the childhood immunisation programme.

Yours sincerely

**DR E M ARMSTRONG** Chief Medical Officer **MISS ANNE JARVIE** Chief Nursing Officer **MR BILL SCOTT** Chief Pharmaceutical Officer

## **1.** The New Vaccines

The following new vaccines will be offered as part of the routine childhood programme. Detailed guidance on these new vaccines can be found in the revised chapters of the UK Health Departments' book *Immunisation against Infectious Disease* (The Green Book). The revised Green Book chapters will be supplied by NHS Health Scotland and can also be accessed from the NHS HealthScotland website - <u>www.healthscotland.com/immunisation</u>.

### For primary immunisation:

• **Pediacel** (diphtheria, tetanus, 5 component acellular pertussis, inactivated polio vaccine, and *Haemophilus influenza* type b vaccine – DTaP/IPV/Hib)

Pediacel (DTaP/IPV/Hib) is recommended for primary immunisation of infants at 2, 3 and 4 months of age. This combination vaccine will replace DTwP-Hib (Act-HIB/DTP) and OPV vaccines that are presently supplied for primary immunisation in children. Pediacel should be given at the same time as the MenC vaccine but at a separate site. JCVI also recommend that Pediacel is used for children up to 10 years of age who are completing their primary immunisation course late.

This vaccine is manufactured by Aventis Pasteur MSD.

### For pre-school boosting:

• **Repevax** (low dose diphtheria, tetanus, 5 component acellular pertussis, and inactivated polio vaccine - dTaP/IPV)

Repevax (dTaP/IPV) is recommended for pre-school boosting at 3 years 4 months of age to 5 years of age. It should be given at least 3 years after completion of the primary course, and can be used for children up to 10 years of age. This combination vaccine will replace the DTaP (Infanrix) and OPV vaccines currently supplied for this age group. Repevax should be given at the same time as the MMR vaccine but in a separate site.

**Please note that Repevax is <u>not</u> recommended for primary immunisation in children of any age**. It is not suitable for this purpose because:

- vaccines containing low dose diphtheria are not suitable for primary immunisation in children under 10 years of age;
- pertussis vaccine is not currently recommended for children aged 10 years or over.

This vaccine is manufactured by Aventis Pasteur MSD.

#### For teenagers:

• **Revaxis** (low dose diphtheria, tetanus, and inactivated polio vaccine - Td/IPV)

Revaxis (Td/IPV) is recommended for boosting teenagers aged 13-18 years old. It can also be used for individuals from 10 years of age and over. Revaxis will replace the Td (Diftavax) and OPV vaccines currently supplied for this age group. Revaxis can also be used for primary immunisation in unvaccinated individuals aged 10 years and over.

Please note that Revaxis is <u>not</u> recommended for use in children under 10 years of age because it has not been studied in this age group, and because children under 10 years of age need to be protected against pertussis.

This vaccine is manufactured by Aventis Pasteur MSD.

#### Summary of Immunisation Schedules with new Vaccines

The schedule including all the proposed new vaccines is summarised in the table below.

When to immunise	What is given	How it is given
Two, three and four months old	Diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and Hib (DTaP/IPV/Hib)	One injection
	Men C	One injection
About 13 months	MMR (measles, mumps and rubella)	One injection
Three years four months to five years old (pre-school)	Diphtheria, tetanus, acellular pertussis, inactivated polio vaccine (dTaP/IPV)	One injection
	MMR	One injection
10 to 14 years old (or sometimes shortly after birth)	BCG (against tuberculosis)	Skin test, then if needed, one injection
13 to 18 years old	Diphtheria, tetanus, and inactivated polio vaccine (Td/IPV)	One injection

# 2. Rationale for the Change

The changes are being made for the following reasons:

• Inactivated polio vaccine (IPV) is appropriate when the risk of importation of 'wild' polio virus is negligible, and IPV does not carry the slight risk of causing vaccine-associated paralytic polio

Oral polio vaccine (OPV) has been used for routine immunisation in the UK because of the continuing risk of importation of wild virus. OPV provides excellent individual immunity and community benefit as contacts of recently immunised children can be protected through acquisition of vaccine virus. However OPV carries a slight risk of vaccine-associated paralytic polio (VAPP) – a risk of about 1 case per million doses given.

The risk of importation of 'wild' polio virus has declined considerably due to the success of the WHO Polio Eradication Programme. This risk and the benefits of OPV need to be balanced against the risks of VAPP from OPV use and the efficacy of IPV. This balance now favours the use of inactivated polio vaccine for routine immunisation in the UK.

• Acellular vaccines tend to cause fewer adverse reactions, particularly in older children and protection against pertussis will be as good as with the whole-cell pertussis vaccine used previously.

The incidence of local and systemic reactions is lower with acellular vaccines compared to whole-cell pertussis vaccines, particularly in older children. Protection against pertussis is not compromised because Pediacel contains an acellular pertussis vaccine that has been shown to offer equal or better protection against clinically typical pertussis disease than whole-cell vaccine.

Since local or general reactions are less frequent after acellular vaccines than whole-cell vaccines, the number of children with such events will be few. There is no benefit in withholding acellular pertussis-containing vaccines in order to reduce the risks of adverse events because the incidence of local reactions to DTaP has been shown to be similar to that for DT.

### • There is no thiomersal (ethylmercury) in these vaccines.

As part of a global goal to reduce avoidable exposure to mercury from sources in general, European and American bodies have recommended that vaccine manufacturers phase out the use of thiomersal wherever possible as a precautionary measure.

Thiomersal is a mercury-based preservative that has been used in vaccines, including the previous DTP-Hib vaccine, for over 60 years. It was added to vaccines to prevent contamination. The World Health Organization's Advisory Committee on Vaccine Safety recently reviewed the safety of thiomersal and concluded that there is no evidence of toxicity in infants and children (or adults) exposed to the levels of thiomersal in vaccines. The UK's advisory organisations on vaccines and other medicines have also reviewed the evidence and found no neurological problems associated with the use of thiomersal in vaccines (see

<u>www.mca.gov.uk/ourwork/monitorsafequalmed/safetymessages/thiomersalstatement\_210203.pdf</u>), and the European advisory body have come to the same conclusion (see <u>www.emea.eu.int/pdfs/human/press/pus/119404en.pdf</u>).

A recent review of the evidence about thiomersal has been carried out by the US Institute of Medicine (IoM). The IoM cleared thiomersal-containing vaccines of any links with autism, and their report is available on their website at <u>www.iom.edu</u>.

# 3. Presentation, Storage, Dosage and Administration

The Summary of Product Characteristics for each vaccine provides detailed information about the vaccine.

## The Vaccines

<u>Primary Immunisations</u>: Pediacel (DTaP/IPV/Hib) is supplied as a suspension in a single dose vial. The vial should be shaken well before the vaccine is drawn up in a syringe for administration.

<u>Pre-school Booster</u>: Repevax (dTaP/IPV) is supplied as a cloudy white suspension for injection in a single dose pre-filled syringe. The suspension may sediment during storage and the syringe should be shaken well to distribute the suspension uniformly before administering the vaccine.

<u>Teenage booster:</u> Revaxis (Td/IPV) is supplied as a cloudy white suspension for injection in a single dose pre-filled syringe. The suspension might sediment during storage and the syringe should be shaken well to distribute the suspension uniformly before injection.

Please note that needles and syringes will need to be ordered to administer pediacel because it is supplied in a single dose vial. See Section 6 on "Consumables".

### Storage

All of the new vaccines should be stored between  $+2^{\circ}C$  and  $+8^{\circ}C$  and protected from light. If a vaccine has been frozen, it must not be used as this can reduce its potency and increase local reactions. Spoiled vaccines should be disposed of by incineration at a suitably authorised facility.

### Administration

The vaccines should be inspected visually for extraneous particulate matter and/or discolouration prior to administration. In the event of either being observed, the vaccine must be discarded.

The vaccines should be administered intramuscularly as this reduces the risk of local reactions. Administration by deep subcutaneous injection may be considered for patients suffering from bleeding disorders, such as thrombocytopenia, because this reduces the risk of haemorrhage.

### **Contraindications**

There are very few individuals who cannot receive Pediacel, Repevax, or Revaxis. The vaccine should not be given to those who have had:

- A confirmed anaphylactic reaction to a previous dose of diphtheria-, tetanus-, pertussis- or polio-containing vaccine; or
- A confirmed anaphylactic reaction to neomycin, streptomycin or polymyxin B (which may be present in the vaccine in trace amount).

Further information on contraindications and cautions is given in the factsheet and in the Green Book, which can be accessed from the NHS Health Scotland website (<u>www.healthscotland.com/immunisation</u>). Where there is doubt, appropriate advice should be sought from a consultant paediatrician, immunisation co-ordinator, or consultant in public health medicine (CD&EH), rather than withholding the vaccine.

### Reporting of Adverse Reactions

Pediacel, Repevax and Revaxis all carry a black triangle ( $\mathbf{\nabla}$ ) symbol. This is a standard symbol added to the product information of a vaccine/medicine during the early stages of marketing to encourage reporting of all suspected adverse reactions. If a doctor, nurse or pharmacist suspects any adverse reaction to one of these vaccines has occurred, they should report it to the Committee on Safety of Medicines using the Yellow Card spontaneous reporting scheme (www.yellowcard.gov.uk).

# 4. Vaccine supply

In the run up to introducing the new vaccines, surgeries are recommended to review their current stocks of the vaccines that will be replaced (Act-HIB DTP, OPV, DTaP and Td). In order to minimise wastage of these vaccines, it is recommended that surgeries ensure that they have adequate supplies to meet their needs up to the change to the new vaccines, but not to hold or order excess stock.

The first deliveries of Pediacel, Repevax and Revaxis will be issued by Vaccine Holding Centres from 27 September and all GP surgeries will have received their first deliveries of the vaccines by 11 October. These should be used from 27 September onwards as they become available. The first delivery of Pediacel will be for four weeks worth of supply. Orders for each of the new vaccines should be placed with Vaccine Holding Centres in the usual way.

Following the first delivery of four weeks worth of stock, <u>all further stocks of Pediacel</u> should be ordered from the Vaccine Holding Centres in the usual way. However because of the need to maintain equitable availability Vaccine Holding Centres will be tracking the previous use of primary vaccines and may find it necessary to cap supplies.

The supply of Pediacel to Vaccine Holding Centres will be made against orders placed with Farillon. The Centres will be advised of the upper limit against which they can order. In the

event that requirement for vaccine is above the allocated limit the Centre should contact Scottish Healthcare Supplies for authorisation prior to placing an order with Farillon.

A list of Vaccine Holding Centres and contacts is given at Appendix A.

# 5. Storage and Disposal of Vaccines no longer used in the Routine Childhood Programme

Deliveries of the new vaccines may put pressure on storage space. Any existing stocks of Act-HIB DTP (DTwP-Hib), Infanrix (DTaP) and OPV should be returned to Vaccine Holding Centres on receipt of the new vaccines. Vaccine Holding Centres will collect remaining supplies of the old stock when it delivers the new stock.

# It is essential that existing stocks of MenC vaccines are <u>not</u> disposed of and are kept for the primary immunisation of babies.

Existing stocks of Diftavax (Td) can be kept for administration at the time of a tetanus-prone wound where appropriate. However if diphtheria or polio vaccination needs to be updated at the same time then Revaxis (Td/IPV) should be used.

# 6. Consumables

Please note that <u>needles and syringes will need to be ordered to administer Pediacel</u> because it is supplied in a single dose vial. The following products are recommended:

FWC518	2ml luer slip syringe
FTR161	orange needle 25g x 16mm
FTR163	blue needle 23g x 25mm
FTR167	green needle 21g x 38mm (for Pediacel only to draw up the vaccine
	into the syringe. Not for administration)

Please note that Repevax and Revaxis are supplied in a pre-filled syringe without a needle. Therefore only needles (orange or blue needles detailed above) will need to be ordered for administration of Repevax and Revaxis. These may be ordered in the usual way.

In order to manage the supplies of these consumables, please place regular orders to meet your needs rather than one very large order just before the switch over is made. Needles and syringes will not be supplied with the vaccine.

# 7. Child Health Systems

The new vaccines provide protection against the same diseases as the vaccines supplied previously. The new vaccines are also given to children at the same ages as the previous vaccines. The Standard Immunisation Recall System (SIRS) and the Child Health Surveillance Programme - School (CHSP – School) users should continue to use these systems in the usual way.

# 8. Patient Group Directions

The requirement for Patient Group Directions (PGD) is described in HDL(2001)7, available from <u>http://www.show.scot.nhs.uk/sehd/mels/HDL2001\_07.htm</u>.

For those surgeries who choose to use PGDs, draft PGDs for Pediacel, Repevax and Revaxis are available at <u>http://www.show.scot.nhs.uk/sehd</u>. NHS Boards may choose to use these drafts as the basis of their PGDs and tailor them to reflect local needs.

## 9. Consent

This section is not intended as legal advice and is for guidance purposes only. Each individual case will be different. Practitioners should seek their own legal advice on the issue of consent in individual cases.

The changes in vaccines will not affect the consent process; consent is required for protection from criminal or civil liability and is not vaccine-product specific.

Consent must be obtained before the administration of all vaccines. Consent obtained before the occasion on which a child is brought for immunisation is only an agreement for the child to be included in the national childhood immunisation programme. It does not mean that consent is in place for each future immunisation. There is no legal requirement for consent to be in writing.

Health professionals involved in immunisation must ensure that :

- parents/carers have access to the new information;
- that there is sufficient opportunity for them to discuss any issues arising, and
- that they are properly informed of the advantages of the new vaccines, and possible side effects and how to treat.

# 10. Funding

The Scottish Executive Health Department has notified the Scottish General Practitioners Committee of the switch to the new vaccines. This change does not have an impact on the remuneration for GPs undertaking the routine childhood immunisation programme.

# **11.** Information for Parents and Healthcare Professionals

New leaflets, and factsheet for parents and healthcare professionals have been produced by NHS Health Scotland and SCIEH. These materials will be sent to GPs by the beginning of September and should be shared with colleagues involved in giving or advising about immunisation including health visitors and practice nurses. Further copies of these resources can be ordered from NHS Board Health Promotion Departments. In case of difficulty contact Agnes Allan, Sales and Distribution Officer, NHS Health Scotland, Fax No: 0131-536 5545 or e-mail: agnes.allan@hebs.scot.nhs.uk.

In addition to the above printed materials, NHS Health Scotland will be launching a new immunisation website – <u>www.healthscotland.com/immunisation</u> - on 25 August. The immunisation website will contain all the new materials as well as translations into Arabic, Bengali, Chinese, Gaelic, Gujarati, Hindi, Punjabi, Urdu, and Turkish. Large print, audio and Braille versions are available on request. A large selection of other immunisation material and research will also be included.

The chapters on diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b for the UK Health Departments' book Immunisation Against Infectious Diseases (the Green Book) have all been updated to reflect the change to the new vaccines. Hard copies of these chapters will be sent to GPs by Health Scotland along with the leaflets and factsheet, and available thev will be on the Health Scotland website (www.healthscotland.com/immunisation). Please note that these new chapters include important new recommendations on a range of important issues in addition to the new vaccines. You are strongly recommended to read this advice.

Further information can be obtained from local Immunisation Co-ordinators.

# VACCINE HOLDING CENTRES & CONTACTS

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