

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

Sir Liam Donaldson
MSc, MD, FRCS(Ed), FRCP, FFPHM

Sarah Mullally
RN, MSc, BSc

Dr Jim Smith
BPharm, PhD, FRPharmS, MCPP,
MIInfSci

Richmond House
79 Whitehall
London SW1A 2NS

PL/CMO/2004/3, PL/CNO/2004/2,
PL/CPHO/2004/3

For action

- PCT Directors of Public Health
 - Immunisation Co-ordinators
 - Consultants in Communicable Disease Control
 - Medical Directors of NHS Trusts
 - Chairs of Primary Care Trusts
 - General Practitioners
 - Directors of Nursing
 - Lead Nurses at PCTs
 - Practice Nurses
 - Community Services Pharmacists
 - Chief Executives of Strategic Health Authorities
 - Chief Executives of NHS Trusts for circulation to all Occupational Health Departments
-

For information

- Regional Directors of Public Health
 - Chairs Infection Control Committees
 - Accident and Emergency Departments
 - All Pharmacists
-

Authorised by the Department of Health:
Gateway no. 2864

10th August 2004

**NEW VACCINATIONS FOR THE
CHILDHOOD IMMUNISATION
PROGRAMME**

Dear Colleague

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

- 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 individual and 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.
- JCVI has 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 that meet the JCVI recommendation are now available. Acellular pertussis vaccines tend to cause fewer adverse reactions than whole cell pertussis vaccines, particularly at the injection site.

Additionally there is no thiomersal in the new vaccines, and hence they satisfy the overall international aim of reducing the exposure of children to mercury from avoidable sources.

In line with these recommendations, from 27 September:

- DTaP/IPV/Hib (brandname: Pediacel) will be supplied for primary immunisation. It replaces the DTwP-Hib and OPV vaccines that are currently given.
- dTaP/IPV (brandname: Repevax) will be supplied for pre-school boosting. It replaces the DTaP and OPV vaccines that are currently given;
- Td/IPV (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 allocation to GP surgeries and pharmacies on their usual delivery days from week commencing 27th September. All GP surgeries and pharmacies will have received one month's stock of the new vaccines by 8th October. Further supplies of Pediacel will be supplied by allocation. Further supplies of Repevax and Revaxis will need to be ordered direct from Farillon.

Syringes and needles need to be ordered in advance from NHS PASA 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 vaccines.

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 with the information materials and which are also available at www.immunisation.nhs.uk. You are strongly recommended to read this advice since there are a number of changes.

Information resources for parents and health professionals are being sent to GP surgeries, Health Promotion Units, pharmacies, NHS Direct Call Centres and Walk-in Centres, Immunisation Co-ordinators, and all those on the Immunisation Information Database by 6th September.

New Vaccinations for the Childhood Immunisation Programme

PL/CMO/2004/3, PL/CNO/2004/2,
PL/CPHO/2004/3

Date: 10th August, 2004

For further information please contact

Dr David Salisbury (Medical issues)
Room 607A

Dorian Kennedy (Policy issues)
Room 606A

Carole Fry (Nursing issues)
Room 609A

Lorraine Gershon (Pharmacy issues),
Area 602A

June Boggis (Supply issues)
Area 602A

Robert Duff (Information issues)
Area 602A

Address

Skipton House
80 London Road
London SE1 6LH

Requests for further copies of this letter should be addressed to:

Department of Health Publications:
Email: dh@prolog.uk.com
Telephone: 08701 555 455
Or write to: Department of Health
PO Box 777, London SE1 6XH

To doctors and practice nurses: for correction or changes of address, practice or name, please contact:

The Medical Mailing Company
PO Box 60, Loughborough
Leicestershire LE11 0WP
Tel: Freephone 0800 626387

For changes to pharmacists contact details please write to:

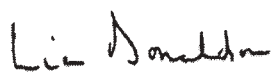
Registration Dept.
RPSGB
1 Lambeth High Street
London SE1 7JN

This letter is also available at:
<http://www.dh.gov.uk/AboutUs/HeadsOfProfession/ChiefMedicalOfficer/CMOLetters/fs/en>

The information resources have been carefully tested with parents and health professionals. We hope these new resources together with the new vaccines, will help you in implementing the changes to the childhood immunisation programme.

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, 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 is available at www.immunisation.nhs.uk.

Further details of the changes to the vaccines supplied are attached in the Annex.



Sir Liam Donaldson
Chief Medical Officer



Sarah Mullally
Chief Nursing Officer



Dr Jim Smith
Chief Pharmaceutical
Officer

Annex

1. The new vaccines

The following new vaccines will be offered as part of the routine childhood programme:

For primary immunisation:

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

We recommend that Pediacel is used for primary immunisation of children at 2, 3 and 4 months of age. We also recommend that it is used for children up to 10 years of age who are completing their primary immunisation course late. 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 in a separate site.

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)

We recommend that Repevax is used 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.

Repevax is *not* 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; and because 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 is recommended for the boosting of teenagers aged 13 to 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.

Revaxis is *not* 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.

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

<i>When to immunise</i>	<i>What is given</i>	<i>How it is given</i>
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 (and 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 because:

- 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 not be compromised with the new vaccines

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 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 www.mca.gov.uk/ourwork/monitorsafequalmed/safetymessages/thiomersalstatement_210203.pdf) and the European advisory body has come to the same conclusion (see www.emea.eu.int/pdfs/human/press/pus/119404en.pdf).

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 at www.iom.edu/report.asp?id=20155.

3. Pharmacy issues – presentation, storage, dosage and administration

The vaccines

Primary immunisations: 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.

Pre-school booster: 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.

Teenage booster: Revaxis (Td/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.

Storage

All of the new vaccines should be stored between +2°C and +8°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.

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 amounts).

Where there is doubt, appropriate advice should be sought from a consultant paediatrician, immunisation co-ordinator, or consultant in communicable disease control, rather than withholding the vaccine.

Reporting of adverse reactions

Pediacel, Repevax and Revaxis all carry a black triangle (▼) 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 delivery of Pediacel, Repevax and Revaxis will be issued by allocation from week commencing 27th September. These vaccines should be used from the date they are received instead of the existing vaccines. All GP surgeries and pharmacies will have received their first delivery by 8 October. The first delivery will be for four weeks worth of supply of each new vaccine.

Following the first delivery of four-weeks-worth of stock, *all further deliveries of Pediacel will occur automatically on a fortnightly basis on your usual day for vaccine delivery.* Each of these further deliveries will be for two weeks worth of stock per delivery, and will be issued by allocation. There is no need for surgeries to place orders for Pediacel. The amount of vaccine required for each delivery point has been identified by the tracking of previous use of primary vaccines.

Following the first delivery of Repevax and Revaxis, *all further supplies of Repevax and Revaxis need to be ordered direct from Farillon.*

Farillon will write to you shortly with details of your allocation, delivery date, and a date when they will collect any stocks of the vaccines being replaced. Please contact Farillon Customer Services (Tel: 01708 330222) if you have any queries about your allocation.

5. Consumables

Please note that *needles and syringes will need to be ordered to administer Pediacel* 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 the administration of Repevax and Revaxis.

These may be ordered through the NHS Logistics Authority in the usual way or for those requiring the special delivery packs, orders may be placed direct with:

B Braun Medical Ltd,
Thorncliffe Park,
Sheffield,
S35 2PW,
Tel: 0114 225 9000
Quoting reference: N3/F/0003/0105/01.

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 by Farillon.

6. 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. However, the introduction of new vaccines may have some impact on Child Health Systems. GPs may need to check arrangements with local providers of Child Health Systems. Immunisation co-ordinators may also be able to assist in facilitating arrangements.

7. Patient Group Directions

The requirement for Patient Group Directions (PGD) is described in HSC 2000/026, available from <http://www.dh.gov.uk/assetRoot/04/01/22/60/04012260.pdf>

For those surgeries that choose to use PGDs, draft PGDs for Pediacel, Repevax and Revaxis are available at www.immunisation.nhs.uk. PCTs may choose to use these drafts as the basis of their PGDs and tailor them to reflect local needs.

8. Consent

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, the possible side effects and how to treat them.

9. Funding

The Department has notified the 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.

10. Information for parents and healthcare professionals

New leaflets, and factsheets for parents and healthcare professionals have been produced by NHS Immunisation Information. These materials will be sent to GP surgeries by 6th September and should be shared with all colleagues involved in giving or advising about immunisation, including health visitors, and practice nurses.

Further copies of these resources can be ordered from Department of Health Publications by e-mail: dh@prolog.uk.com; or telephone: 08701 555 455 (please quote the 5-digit Smart code printed on the back of the materials).

In addition to the above printed materials, the www.immunisation.nhs.uk website has been revised and updated with information on the new vaccines; an interactive Q&A facility; and downloadable resource materials.

The chapters on diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b for the 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 have been sent to GP surgeries along with the leaflets and factsheets, and they will be available at www.immunisation.nhs.uk. Please note that these new chapters include important new recommendations on a range of important issues in addition to the new vaccines.

11. Storage and disposal of vaccines no longer used in the routine childhood programme

Any existing stocks of Act-HIB DTP (DTwP-Hib), Infanrix (DTaP) and OPV should be returned to Farillon or disposed of locally on receipt of the new vaccines. Farillon will advise the collection of remaining supplies of the stocks of old vaccine in their letter to surgeries.

It is essential that existing stocks of MenC vaccines 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 polio, or polio and diphtheria, vaccination needs to be updated at the same time then Revaxis (Td/IPV) should be used.