

From the Chief Medical Officer  
Dr Henrietta Campbell CB

## HSS(MD)24/2004

All General Practitioners (*for onward dissemination to practice staff*)

All Locum General Practitioners

Chief Executives of Health and Social Services Board

Chief Executives of Health and Social Services Trusts

Chief Executive, Health Promotion Agency

Directors of Public Health (*for onward dissemination to CPHM*)

Medical Directors Health and Social Services Trusts

Directors of Nursing Health and Social Services Boards

Directors of Nursing Health and Social Services Trusts (*for onward dissemination to community nurses and health visitors*)

Directors of Primary Care, Health and Social Services Boards

Directors of Pharmacy, Health and Social Services Boards

Directors of Pharmacy, Health and Social Services Trusts

Consultants in Communicable Disease Control, Health and Social Services Boards

Consultant Paediatricians

Child Health System Managers

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Your Ref:

Our Ref: HSS(MD)24/2004

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Dear Colleague

### CHILDHOOD IMMUNISATION PROGRAMME

The purpose of this letter is to provide you with important information about forthcoming changes to the vaccines provided for the routine childhood immunisation programme in Northern Ireland. These changes are being made following the recommendation of the Joint Committee on Vaccination and Immunisation (JCVI).

#### Background

1. 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.

2. 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 less 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 2004:

- 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 preschool 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.

3. The new vaccines will be supplied from your designated hospital pharmacy in the normal way. Supplies of the vaccines are not available through community pharmacies. GP Practices and clinics should order the new vaccines in the normal way **in advance of the change over**. All supply enquiries should be directed to your designated hospital pharmacy.

Further information on ordering arrangements and local availability of supplies of the new vaccines will be issued to designated hospital pharmacies by the Regional Pharmaceutical Procurement Service (Tel: 028 9055 2386)

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

4. Information resources for parents and health professionals are being sent to GP surgeries, Health Promotion Units and Child Health System Managers. These should be available in early September. They will also be made available on the DHSSPS website at [www.dhsspsni.gov.uk/publichealth](http://www.dhsspsni.gov.uk/publichealth) and the website of the Health Promotion Agency at [www.healthpromotionagency.org.uk](http://www.healthpromotionagency.org.uk). We hope these new information materials will help you in implementing the changes to the childhood immunisation programme.

5. 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](http://www.immunisation.nhs.uk). **You are strongly recommended to read this advice since there are a number of changes.**
6. 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](http://www.immunisation.nhs.uk).
7. Full details of the changes to the vaccines supplied are attached in the Annex.

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Yours sincerely

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Mr A Hamilton, Director of Finance, DHSSPS  
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Mr C Shannon, Information Office, DHSSPS  
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Mrs D Kenny, Health Development Director, DHSSPS  
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Regional Immunisation Committee

This letter is available at [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk) and also on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS.

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### 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:

<b>When to Immunise</b>	<b>Diseases Vaccine Protects Against</b>	<b>How it is Given</b>
2, 3 and 4 months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Hib	One injection
	Meningitis C	One injection
Around 15 months old	Measles, mumps and rubella	One injection
3 to 5 years old	Diphtheria, tetanus, pertussis and polio	One injection
	Measles, mumps and rubella	One injection
10 to 14 years old (and sometimes shortly after birth)	Tuberculosis (BCG vaccine)	Skin test, then one injection, if needed
14 to 18 years old	Tetanus, diphtheria and polio	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](http://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](http://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](http://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](http://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 new vaccines should be used from the w/c 27<sup>th</sup> September 2004 instead of the existing vaccines. Please liaise with your local hospital pharmacy regarding local arrangements for supply and distribution of the new vaccines and uplift of the existing vaccines. Please do not destroy the existing vaccines locally as these must be returned to your designated hospital pharmacy. Please liaise with you local hospital pharmacy regarding uplift arrangements.

## **5. Consumables**

Please note that *needles and syringes will need to be ordered (from your usual source of supply) to administer Pediacel* because it is supplied in a single dose vial. The following products are recommended:

2ml luer slip syringe

orange needle 25g x 16mm

blue needle 23g x 25mm

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.

## **6. Child Health System**

The CHS is being updated to reflect these changes. 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.

## **7. Consent**

The changes in vaccines will not affect the consent process, which 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.

## **8. Funding**

This change does not have an impact on the remuneration for GPs undertaking the routine childhood immunisation programme.

## **9. Patient Group Directions (PGDs)**

For those practitioners who use PGDs new ones will be required for Pediacel, Repevax and Revaxis and should be developed to reflect local needs.

## **10. Information for parents and healthcare professionals**

New leaflets, and factsheets for parents and healthcare professionals have been produced by the Health Promotion Agency, Northern Ireland on behalf of DHSSPS. These materials will be sent to GP surgeries by in early September and should be shared with all colleagues involved in giving or advising about immunisation, including health visitors, and practice nurses.

Further information is also available at - [www.immunisation.nhs.uk](http://www.immunisation.nhs.uk).  
[www.dhsspsni.gov.uk/publichealth](http://www.dhsspsni.gov.uk/publichealth)

## Professional Information

The detailed 'flickover' information leaflet for health professionals on Childhood Immunisation has been updated and will be circulated in September as part of a comprehensive professional pack. 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 will also be included in the professional pack sent to health professionals along with the leaflets and factsheets. They will also be available at [www.immunisation.nhs.uk](http://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.

All the information materials used in the Childhood Immunisation Programme will be available on the DHSSPS website at [www.dhsspsni.gov.uk/publichealth](http://www.dhsspsni.gov.uk/publichealth) and also on the website of the Health Promotion Agency at [www.healthpromotionagency.org.uk](http://www.healthpromotionagency.org.uk).

### 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 your local designated hospital pharmacy. Please do not dispose of stock locally. **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 tetanusprone 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.**