

NATIONAL ASSEMBLY FOR WALES

SUBORDINATE LEGISLATION

2006 No.

NATIONAL HEALTH SERVICE ACT 1977

**The Directions to Local Health Boards as to the Statement of
Financial Entitlements (Amendment) (No. 3) Directions 2006**

Made - - - - - *19 December 2006*

Coming into force - - - - - *20 December 2006*

The National Assembly for Wales, in exercise of the powers conferred by section 28T of the National Health Service Act 1977(1) hereby gives the following Directions:

Title, commencement, application and interpretation

1.—(1) The title of these directions is the Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2006.

(2) These Directions come into force on 20 December 2006 but will have effect as from 4 September 2006.

(3) These Directions are given to Local Health Boards and apply in relation to Wales.

Amendments to the SFE

2. The directions given by the National Assembly for Wales in the Directions to Local Health Boards as to the Statement of Financial Entitlements under section 28T of the National Health Service Act 1977 which came into force on 30 April 2005(2) are further amended as follows.

Amendments to the Table of Contents

3. In the Table of Contents—

(a) in Part 4 (payments for specific purposes)—

(i) before Section 9 (payments for locums covering maternity, paternity and adoption leave), insert the following—

(1) 1977 c.49. Section 28T was inserted by section 175 of the Health and Social Care (Community Health and Standards) Act 2003 (c.43).

(2) These Directions were amended by the Statement of Financial Entitlements (Amendment)(No.2)(Wales) Directions 2005, which were made on 21 July 2005, by the Statement of Financial Entitlements (Amendment)(Wales) Directions 2006 which came into force on 1 February 2006, by the Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2006 which came into force on 1 April 2006 and by the Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2006 which came into force on 16 November 2006.

“8A. PNEUMOCOCCAL VACCINATION AND HIB/MENC BOOSTER VACCINATION

Payment for administration of PCV vaccinations and Hib/MenC vaccinations as part of the routine childhood immunisation schedule

Payment for administration of PCV vaccinations other than as part of the routine childhood immunisation schedule

Children at increased risk of pneumococcal infection

Children over the age of 13 months but under 5 years who have previously had invasive pneumococcal disease

Children with an unknown or incomplete vaccination status

Eligibility for payment

Claims for payment

Conditions attached to payment

8B. ADMINISTRATION OF PNEUMOCOCCAL VACCINATION AS PART OF THE PNEUMOCOCCAL CATCH-UP CAMPAIGN

Payment for administration of PCV vaccinations as part of the Pneumococcal Catch-up campaign

Eligibility for payment

Claims for payment

Conditions attached to payment”, and

(ii) in Section 14 (doctors’ retainer scheme), after “payments in respect of sessions undertaken by members of the Scheme”, insert the following—

“provisions in respect of leave arrangements”; and

(b) at the end of the list of Annexes, add ***“I. Pneumococcal and Hib/MenC booster vaccinations and Pneumococcal Catch-up Campaign”***.

Amendment to Section 8

4.—(1) Section 8 (Childhood Immunisations Scheme) is amended as follows.

(2) At the start of sub-paragraph 8.3(b), insert “subject to paragraph 8.3A.”.

(3) After paragraph 8.3 insert the following—

“8.3A In establishing whether the required percentage of the cohort of children referred to in paragraph 8.3 have completed the recommended immunisation courses referred to in that paragraph, the LHB is not required to determine whether any of that cohort have received the Hib/MenC booster recommended, in the provisions set out at Annex I to this SFE, for administration around the age of 12 months. The administration of that Hib/MenC booster vaccination is not a requirement for payment under this Section.”.

Insertion of Sections 8A and 8B

5. Before Section 9 (payments for locums covering maternity, paternity and adoption leave), insert the following Sections—

“SECTION 8A – Pneumococcal vaccination and Hib/MenC booster vaccination

8A.1 Changes were introduced to the routine childhood immunisation programme with effect from 4 September 2006. Details of those changes, which relate to the introduction of

pneumococcal vaccine into the routine childhood immunisation programme, changes to the schedule for the Meningitis C (Men C) and Haemophilus influenzae type B (HiB) vaccinations, and a pneumococcal vaccination catch-up programme for children aged under 2 years, were set out in Welsh Health Circular (2006) 018 dated 12 July 2006. The provisions contained in that Welsh Health Circular are set out in Annex I to this SFE.

8A.2 Childhood immunisation and pre-school booster services are classified as Additional Services. This Section makes provision in respect of payments to be made in respect of the administration by a contractor, which is contracted to provide the childhood immunisation and pre-school booster Additional Service, of the pneumococcal conjugate vaccine (PCV) and the combined Hib and Men C booster vaccine (Hib/MenC) as part of the routine childhood immunisation schedule and in certain non-routine cases.

8A.3 The provisions of this section apply with effect from 4 September 2006.

8A.4 Payments in respect of the administration by a contractor, who is contracted to provide the childhood immunisations and pre-school booster Additional Service, of the pneumococcal conjugate vaccine (PCV) as part of the catch-up programme for children who were aged over two months but under 2 years on 4 September 2006 and who, because they had already started their routine immunisation programme, cannot receive the three pneumococcal vaccinations in accordance with the table set out in paragraph 8A.8, are dealt with separately in Section 8B.

8A.5 References in this Section to the age of a child expressed in months are references to calendar months. Where reference is made to a vaccination being administered at or around a certain age, this is an indication of the recommended schedule for administration of the vaccine contained in the provisions as set out in Annex I to this SFE. The specific timing of the administration of the vaccination, which should be within the parameters of the recommended schedule, is a matter for the clinical judgement of the relevant health care professional.

Payment for administration of PCV vaccinations and Hib/MenC vaccinations as part of the routine childhood immunisation schedule

8A.6 The LHB must pay to a contractor who qualifies for the payment, a payment of £15.02 in respect of each child registered with the contractor—

- (a) who has received, as part of their routine childhood immunisation schedule, all four of the vaccinations set out in the table at paragraph 8A.8, namely the series of three PCV vaccinations to be administered at two months, four months and around 13 months, and the Hib/MenC booster vaccination which is to be administered at around 12 months; and
- (b) in respect of whom the contractor administered the final completing vaccination.

8A.7 For the purpose of paragraph 8A.6(b), the final completing vaccination means the third in the series of three PCV vaccinations which is scheduled, in the table at paragraph 8A.8, to be administered at around 13 months.

8A.8 The table below sets out the schedule for the administration of the PCV and the Hib/MenC vaccinations as part of the routine childhood immunisation schedule.

| <i>When to immunise</i> | <i>What is given</i> | <i>How vaccine is given</i> |
|--------------------------------|--|------------------------------------|
| Two months old | Pneumococcal (PCV) | One injection |
| Four months old | Pneumococcal (PCV) | One injection |
| Around 12 months | Haemophilus influenzae type b, Meningitis C (Hib/MenC) | One injection |
| Around 13 months | Pneumococcal (PCV) | One injection |

Payment for administration of PCV vaccinations other than as part of the routine childhood immunisation schedule

8A.9 The LHB must pay to a contractor who qualifies for the payment, a payment of £15.02 in respect of each child registered with the contractor who has received the PCV vaccination in any of the circumstances set out in paragraphs 8A.11 to 8A.15 and in respect of whom the contractor administered the final completing vaccination, but only where the equivalent PCV vaccinations cannot be administered as part of the pneumococcal catch-up campaign under Section 8B. If the equivalent PCV vaccination can be administered as part of the pneumococcal catch-up campaign the contractor is not entitled to any payment under this Section.

Children at increased risk of pneumococcal infection

8A.10 The table below sets out what are, for the purposes of this Section, the specific pneumococcal clinical risk groups for children.

| <i>Clinical risk group</i> | <i>Examples (decision based on clinical judgement)</i> |
|---|---|
| Asplenia or dysfunction of the spleen | This includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction. |
| Chronic respiratory disease | This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neuromuscular disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below) is needed. |
| Chronic heart disease | This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure. |
| Chronic renal disease | This includes nephrotic syndrome, chronic renal failure, renal transplantation. |
| Chronic liver disease | This includes cirrhosis, biliary atresia, chronic hepatitis |
| Diabetes (requiring insulin or oral hypoglycaemic drugs) | This includes type I diabetes requiring insulin or type 2 diabetes requiring oral hypoglycaemic drugs. It does not include diabetes that is diet controlled. |
| Immunosuppression | Due to disease or treatment, including asplenia or splenic dysfunction and HIV infection at all stages. Patients undergoing chemotherapy leading to immunosuppression. Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone 20mg or more per day (any age), or for children under 20kg, a dose of ≥ 1 mg/kg/day. Some immunocompromised patients may have a suboptimal immunological response to the vaccine. |

| | |
|---|--|
| Individuals with cochlear implants | It is important that immunisation does not delay the cochlear implantation. Where possible, pneumococcal vaccination should be completed at least 2 weeks prior to surgery to allow a protective immune response to develop. In some cases it will not be possible to complete the course prior to surgery. In this instance, the course should be started at any time prior to or following surgery and completed according to the immunisation schedule. |
| Individuals with Cerebrospinal fluid leaks | This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery. |

8A.11 Where a child who is in any of the pneumococcal clinical risk groups set out in the table in paragraph 8A.10 presents late for vaccination (that is, not in accordance with the routine schedule set out in paragraph 8A.8), and —

- (a) consequently cannot receive, and has not received, the four vaccinations referred to in paragraph 8A.6(a) in accordance with the routine schedule set out in the table in paragraph 8A.8; but
- (b) who nevertheless still presents in time to enable him or her to receive, and did receive, two doses of PCV before the age of 12 months, the Hib/Men C booster at around the age of 12 months and a third dose of PCV at around the age of 13 months,

the LHB must pay to the contractor administering the final completing vaccination a payment of £15.02 in respect of that child. The third dose of PCV is considered the final completing vaccination for this purpose.

8A.12 Where a child over the age of 12 months but under the age of 5 years and who is in any of the clinical risk groups set out in the table in paragraph 8A.10 presents late for vaccination (that is, not in accordance with the routine schedule set out in paragraph 8A.8), and —

- (a) consequently cannot receive, and has not received, two doses of PCV before the age of 12 months, the Hib/Men C booster at around the age of 12 months and a third dose of PCV at around the age of 13 months; but
- (b) who nevertheless receives either a single dose of PCV or, if he has asplenia, splenic dysfunction or is immunocompromised, two doses of PCV, the second of which is administered two months after the first dose,

the LHB must pay to the contractor administering the final completing vaccination a payment of £15.02 in respect of that child. The single dose of PCV or, in the case of a child where a second dose of PCV is required, the second dose of PCV is considered the final completing vaccination for this purpose.

Children over the age of 13 months but under 5 years who have previously had invasive pneumococcal disease

8A.13 Where a child who is over 13 months but under 5 years and who has previously had invasive pneumococcal disease receives a single dose of PCV in accordance with the recommendation contained in paragraph 6 of the provisions set out at Annex I to this SFE, the LHB must pay to the contractor administering the final completing vaccination a payment of £15.02 in respect of that child, unless a payment is otherwise payable for that same final completing vaccination under paragraph 8A.12, 8A.15 or Section 8B. The single dose of PCV is considered the final completing vaccination for this purpose.

Children with an unknown or incomplete vaccination status

8A.14 Where a child who has an unknown or incomplete vaccination status receives vaccinations sufficient to ensure that he or she has received two doses of PCV before the age of 12 months, the Hib/MenC booster at around the age of 12 months and a third dose of PCV at around the age of 13 months, the LHB must pay to the contractor administering the final completing vaccination a payment of £15.02 in respect of that child. The third dose of PCV is considered the final completing vaccination for this purpose.

8A.15 Where a child who has an unknown or incomplete vaccination status and is too old to be able to receive two doses of PCV before the age of 12 months, the Hib/MenC booster at around the age of 12 months and a third dose at around the age of 13 months, receives a single dose of PCV prior to the age of 24 months, the LHB must pay to contractor who administers the final completing vaccination a payment of £15.02 in respect of that child. The single dose of PCV is considered the final completing vaccination for this purpose.

Eligibility for payment

8A.16 A contractor is only eligible for a payment under this Section in circumstances where the following conditions are met —

- (a) the contractor is contracted to provide the childhood immunisation and pre-school booster Additional Service;
- (b) the child in respect of whom the payment is claimed was on the contractor's list of registered patients at the time the final completing vaccination was administered;
- (c) the contractor administers the final completing vaccination to the child in respect of whom the payment is claimed;
- (d) subject to sub-paragraph (e), the child in respect of whom the payment is claimed is aged around 13 months when the final completing vaccination is administered;
- (e) in the case of payments in respect of vaccinations administered in accordance with paragraphs 8A.12 or 8A.13, the child must be under 5 years when the final completing vaccination is administered and in the case of vaccinations administered in accordance with paragraph 8A.15, the child must be under 2 years when the final completing vaccination is administered;
- (f) the contractor does not receive any payment from any other source in respect of any of the series of three PCV vaccinations and the Hib/MenC booster vaccination set out in the table at paragraph 8A.8 or in respect of any vaccination administered under any of the circumstances set out in paragraphs 8A.11 to 8A.15 of this Section (if he or she does receive any such payment in respect of any child from any other source, the LHB must give serious consideration to recovering any payment made under this Section in respect of that child pursuant to paragraph 18.1(a)); and
- (g) the contractor submits the claim within 6 months of administering the final completing vaccination.

8A.17 The LHB may set aside the requirement that the contractor submit the claim within 6 months of administering the final completing vaccination if it considers it reasonable to do so.

8A.18 The contractor is not entitled to —

- (a) payment of more than £15.02 in respect of any child under this Section, other than where —
 - (i) the contractor claims for payment for a final completing vaccination administered under the circumstances set out in paragraph 8A.13, and
 - (ii) by virtue of that paragraph, the contractor is entitled to a payment under that paragraph, irrespective of any previous payment made in respect of that child under the provisions of this Section;

- (b) any payment under this Section in addition to any payment made in respect of a final completing vaccination administered to the same child under the pneumococcal catch-up campaign provided for under Section 8B, other than where —
 - (i) the contractor claims for payment for a final completing vaccination administered under the circumstances set out in paragraph 8A.13, and
 - (ii) that final completing vaccination is in addition to any final completing vaccination administered under the provisions of Section 8B.

Claims for payment

8A.19 The contractor is to submit claims in respect of final completing vaccinations after they have been administered at a frequency to be agreed between the LHB and the contractor (which must be a frequency which provides for the claim to be submitted within 6 months of administering the final completing vaccination), or, if agreement cannot be reached, within 14 days of the end of the month during which the final completing vaccination was administered. Any amount payable falls due on the next date, following the expiry of 14 days after the claim is submitted, when the contractor's Payable GSMP falls due.

8A.20 LHBs must ensure that the receipt and payment in respect of any claims are properly recorded and that each such claim has a clear audit trail.

Conditions attached to payment

8A.21 A payment under the provisions of this Section is only payable if the contractor satisfies the following conditions—

- (a) the contractor must supply the LHB with the following information in respect of each child for which a payment is claimed—
 - (i) the name of the child,
 - (ii) the date of birth of the child,
 - (iii) the NHS number, where known, of the child,
 - (iv) subject to paragraph (v) below, confirmation that the child has received three doses of PCV and one dose of Hib/MenC in accordance with the table at paragraph 8A.8,
 - (v) if the claim is made in the circumstances set out in paragraph 8A.12, 8A.13 or 8A.15, confirmation that all required vaccinations have been administered, and
 - (vi) the date of the final completing vaccination, which must have been administered by the contractor,but where a parent or carer objects to details of the child's name or date of birth being supplied to the LHB, the contractor need not supply such information to the LHB but must supply the child's NHS number;
- (b) the contractor must provide appropriate information and advice to the parent or carer of the child, and, where appropriate, also to the child, about pneumococcal vaccinations and the Hib/MenC booster vaccination;
- (c) the contractor must record in the child's records, kept in accordance with paragraph 72 of Schedule 6 to the 2004 Regulations, any refusal of an offer of a pneumococcal vaccination or a Hib/MenC booster vaccination;
- (d) where a pneumococcal vaccination or a Hib/MenC booster vaccination is administered, the contractor must record in the child's records, kept in accordance with paragraph 72 of Schedule 6 to the 2004 Regulations, those matters set out in paragraph 5(2)(d) of Schedule 2 to the 2004 Regulations;

- (e) the contractor must ensure that any health care professional who performs any clinical service in connection with the administration of the vaccine has such clinical experience and training as are necessary to enable him or her to properly perform such services and that such health care professionals are trained in the recognition and initial treatment of anaphylaxis;
- (f) the contractor must make available to the LHB any information which the LHB does not have but needs, and the contractor either has or could be reasonably expected to obtain, in order to form its opinion on whether the contractor is eligible for payment under the provisions of this Section;
- (g) the contractor must make any returns required of it (whether computerised or otherwise) to the Exeter Registration System, and do so promptly and fully; and
- (h) all information provided pursuant to or in accordance with this paragraph must be accurate.

8A.22 If the contractor breaches any of these conditions, the LHB may, in appropriate circumstances, withhold payment of any, or any part of, the payment due under this Section.

SECTION 8B – Administration of pneumococcal vaccination as part of the pneumococcal catch-up campaign

8B.1 Changes were introduced to the routine childhood immunisation programme with effect from 4 September 2006. Details of those changes, which relate to the introduction of pneumococcal vaccine into the routine childhood immunisation programme, changes to the schedule for the Meningitis C (Men C) and Haemophilus influenzae type B (HiB) vaccinations, and a Pneumococcal vaccination catch-up programme for children aged under 2 years, were set out in Welsh Health Circular (2006) 018 dated 12th July 2006. The provisions contained in that Welsh Health Circular are set out in Annex I to this SFE.

8B.2 Childhood immunisation and pre-school booster services are classified as Additional Services. This Section makes provision in respect of payments in respect of the administration by a contractor, which is contracted to provide the childhood immunisation and pre-school booster Additional Service, of the pneumococcal conjugate vaccine (PCV) as part of the catch-up programme for children who were aged over two months but under 2 years on 4 September 2006 and who, because they had already started their routine immunisation programme, cannot receive the three PCV vaccinations in accordance with the schedule in the table set out in paragraph 8A.8.

8B.3 The provisions of this Section apply with effect from 4 September 2006.

8B.4 Payments in respect of the administration by a contractor, which is contracted to provide childhood immunisation and pre-school booster Additional Services, of the pneumococcal conjugate vaccine (PCV) and the combined Hib and Men C booster vaccine (Hib/MenC) as part of the routine childhood immunisation schedule, and in certain non-routine cases, are dealt with separately in Section 8A.

8B.5 References in this Section to the age of a child expressed in months are references to calendar months. Where reference is made to a vaccination being administered at or around a certain age, this is an indication of the recommended schedule for administration of the vaccine contained in the provisions as set out in Annex I to this SFE. The specific timing of the administration of the vaccination, which should be within the parameters of the recommended schedule, is a matter for the clinical judgement of the relevant health care professional.

Payment for administration of PCV vaccinations as part of the Pneumococcal Catch-up campaign

8B.6 The pneumococcal catch-up campaign is aimed at the cohort of children who are over 2 months and under 2 years on 4 September 2006 and who consequently do not receive their PCV vaccinations as part of their routine childhood immunisations in accordance with the schedule set out at paragraph 8A.8. The aim of the catch-up campaign is to ensure that the target cohorts are offered vaccinations appropriate to their age within 6 months of 4 September 2006.

8B.7 The LHB must pay to a contractor who qualifies for the payment, a payment of £7.51 in respect of each child registered with the contractor —

- (a) who has received, as part of the pneumococcal catch-up campaign, the vaccinations set out in the table in paragraph 8B.8 appropriate to their age group; and
- (b) in respect of whom the contractor administered the final completing vaccination, as determined by reference to the third column in the table in paragraph 8B.8.

8B.8 The table below sets out the schedule for the administration of the PCV vaccinations as part of the pneumococcal catch-up campaign.

| <i>Age group</i> | <i>Vaccination required and when required</i> | <i>Final completing vaccination</i> | <i>How the vaccine is given</i> |
|--|--|---|--|
| Children born between 5 September 2004 and 3 August 2005 | One dose of PCV to be administered between 4 September 2006 and 31 March 2007 | The final completing vaccination is the dose of PCV administered between 4 September 2006 and 31 March 2007 | One injection |
| Children born between 4 August 2005 and 3 February 2006 | One dose of PCV to be administered to the child around the age of 13 months | The final completing vaccination is the dose of PCV administered around the age of 13 months | One injection |
| Children born between 4 February 2006 and 3 July 2006 | Two doses of PCV, separated by a period of two months, before the age of 12 months and followed by a further dose of PCV around the age of 13 months | The final completing vaccination is the third of the three required doses of PCV which is administered to the child around the age of 13 months | On each occasion one injection |

Eligibility for payment

8B.9 A contractor is only eligible for a payment under this Section in circumstances where the following conditions are met—

- (a) the contractor is contracted to provide the childhood immunisation and pre-school booster Additional Service;

- (b) the child in respect of whom the payment is claimed was on the contractor's list of registered patients at the time the final completing vaccination was administered;
- (c) the contractor administers the final completing vaccination to the child in respect of whom the payment is claimed;
- (d) the child in respect of whom the payment is claimed was, on 4 September 2006, aged over two months and under 2 years;
- (e) the contractor does not receive any payment from any other source in respect of any of the PCV vaccinations (if he or she does receive any such payment in respect of any child from any other source, the LHB must give serious consideration to recovering any payment made under this Section in respect of that child pursuant to paragraph 18.1(a)); and
- (f) the contractor submits the claim within 6 months of administering the final completing vaccination.

8B.10 The LHB may set aside the requirement that the contractor submit the claim within 6 months of administering the final completing vaccination if it considers it reasonable to do so.

8B.11 The contractor is not entitled to —

- (a) payment of more than £7.51 in respect of any child under this Section;
- (b) any payment under this Section in addition to any payment made in respect of a final completing vaccination administered to the same child under the provisions of Section 8A, other than where —
 - (i) the contractor claims for payment for a final completing vaccination administered under the circumstances set out in paragraph 8A.13, and
 - (ii) that final completing vaccination is in addition to any final completing vaccination administered under the provisions of this Section.

Claims for payment

8B.12 The contractor is to submit claims in respect of final completing vaccinations after they have been administered at a frequency to be agreed between the LHB and the contractor (which must be a frequency which provides for the claim to be submitted within 6 months of administering the final completing vaccination), or, if agreement cannot be reached, within 14 days of the end of the month during which the final completing vaccination was administered. Any amount payable falls due on the next date, following the expiry of 14 days after the claim is submitted, when the contractor's Payable GSMP falls due.

8B.13 LHBs must ensure that the receipt and payment in respect of any claims are properly recorded and that each such claim has a clear audit trail.

Conditions attached to payment

8B.14 A payment under the provisions of this Section is only payable if the contractor satisfies the following conditions—

- (a) the contractor must supply the LHB with the following information in respect of each child for which a payment is claimed—
 - (i) the name of the child,
 - (ii) the date of birth of the child,
 - (iii) the NHS number, where known, of the child,
 - (iv) confirmation that the child has received the required dose or doses of PCV in accordance with the table at paragraph 8B.8, and
 - (v) the date of the final completing vaccination, which must have been administered by the contractor,

but where a parent or carer objects to details of the child's name or date of birth being supplied to the LHB, the contractor need not supply such information to the LHB but must supply the child's NHS number;

- (b) the contractor must provide appropriate information and advice to the parent or carer of the child, and, where appropriate, also to the child, about pneumococcal vaccinations;
- (c) the contractor must record in the child's records, kept in accordance with paragraph 72 of Schedule 6 to the 2004 Regulations, any refusal of an offer of a pneumococcal vaccination;
- (d) where a pneumococcal vaccination is administered, the contractor must record in the child's records, kept in accordance with paragraph 72 of Schedule 6 to the 2004 Regulations, those matters set out in paragraph 5(2)(d) of Schedule 2 to the 2004 Regulations;
- (e) the contractor must ensure that any health care professional who performs any clinical service in connection with the administration of the vaccine has such clinical experience and training as are necessary to enable him or her to properly perform such services and that such health care professionals are trained in the recognition and initial treatment of anaphylaxis;
- (f) the contractor must make available to the LHB any information which the LHB does not have but needs, and the contractor either has or could be reasonably expected to obtain, in order to form its opinion on whether the contractor is eligible for payment under the provisions of this Section;
- (g) the contractor must make any returns required of it (whether computerised or otherwise) to the Exeter Registration System, and do so promptly and fully; and
- (h) all information provided pursuant to or in accordance with this paragraph must be accurate.

8B.15 If the contractor breaches any of these conditions, the LHB may, in appropriate circumstances, withhold payment of any, or any part of, the payment due under this Section.”.

Substitution of Section 14

6. For Section 14 (Doctors' Retainer Scheme) substitute the following—

“14.1 This is an established Scheme designed to keep doctors who are not working in general practice in touch with general practice.

Payments in respect of sessions undertaken by members of the Scheme

14.2 Subject to paragraph 14.2A, where —

- (a) a contractor who is considered as a suitable employer of members of the Doctors' Retainer Scheme by the Dean of General Practice, University Wales College of Medicine employs or engages a member of the Doctors' Retainer Scheme; and
- (b) the service sessions for which the member of the Doctors' Retainer Scheme is employed or engaged by that contractor have been arranged by the Dean of General Practice, University Wales College of Medicine,

the LHB must pay to that contractor under its GMS contract £59.18 in respect of each full session that the member of the Doctors' Retainer Scheme undertakes for the contractor in any week, up to a maximum of four sessions per week.

Provisions in respect of leave arrangements

14.2A The LHB must pay to the contractor under its GMS contract any payment payable under paragraph 14.2 in respect of any session which the member of the Doctors'

Retainer Scheme is employed or engaged to undertake but which that member does not undertake because they are absent due to leave related to—

- (a) annual holiday up to a maximum number of sessions annually equivalent to 6 weeks' worth of arranged sessions for the member of the Doctors' Retainer Scheme;
- (b) maternity, paternity or adoption, in accordance with the circumstances and for the periods referred to in Section 9 (payments for locums covering maternity, paternity and adoption leave);
- (c) parental leave, in accordance with statutory entitlements (except that the normal statutory qualifying period of one year's service with the contractor does not apply);
- (d) sickness, for a reasonable period as agreed by the contractor and the LHB;
- (e) an emergency involving a dependent, in accordance with employment law and any guidance issued by the Department of Trade and Industry;
- (f) other pressing personal or family reasons where the contractor and the LHB agree that the absence of the member of the Doctors' Retainer Scheme is necessary and unavoidable.

Payment conditions

14.3 Payments under this section are to fall due at the end of the month in which the session to which the payment relates takes place. However, the payments, or any part thereof, are only payable if the contractor satisfies the following conditions—

- (a) the contractor must inform the LHB of any change to the member of the Doctors' Retainer Scheme's working arrangements that may affect the contractor's entitlement to a payment under this section;
- (b) the contractor must inform the LHB of any absence on leave of the member of the Doctors' Retainer Scheme and the reason for such absence;
- (c) in the case of any absence on leave in respect of which there are any matters to be agreed between the contractor and the LHB in accordance with paragraph 14.2A above, the contractor must make available to the LHB any information which the LHB does not have but needs, and which the contractor either has or could be reasonably expected to obtain, in order to form an opinion in respect of any of the matters which are to be agreed between the contractor and the LHB;
- (d) the contractor must inform the LHB if the doctor in respect of whom the payment is made ceases to be a member of the Doctors' Retainer Scheme, or if it ceases to be considered a suitable employer of members of the Doctors' Retainer Scheme by the Dean of General Practice, University Wales College of Medicine;

14.4 If a contractor breaches any of these conditions, the LHB may, in appropriate circumstances, withhold payment of any payment otherwise payable under this Section.”

Amendment to Section 15

7. In Section 15 (dispensing), for sub-paragraph 15.6(a) (which relates to products not covered by Section 15) substitute the following—

- “(a) MMR (Measles, Mumps and Rubella); BCG (Bacillus Calmette-Guérin); Tuberculin Purified Protein Derivative; Meningococcal C conjugate vaccine (for children under 5 and persons entering the first year of higher education); DTaP/IPV/HiB (Diphtheria/Tetanus/Pertussis/Inactivated Polio/Haemophilus influenzae type B); dTaP/IPV (low dose Diphtheria/Tetanus/Pertussis/Inactivated Polio); DTaP/IPV (Diphtheria/Tetanus/ Pertussis/Inactivated Polio); Td/IPV (Diphtheria/Tetanus/Inactivated Polio); Hib/MenC (Haemophilus influenzae type B/meningitis C) and PCV (pneumococcal); ”.

Amendment to Annex A

8. In Part 2 of Annex A (Glossary – Definitions), after the definition of “Adjusted Practice Disease Factor” insert the following definition—

““Childhood Immunisations and Pre-school Boosters” is to be construed as a reference to the Childhood Vaccinations and Immunisations additional service referred to in the 2004 Regulations;”.

Addition of Annex I

9. After Annex H (Dispensary Services Quality Scheme), insert the Annex I (Annex I. Pneumococcal and Hib/MenC Booster Vaccinations and Pneumococcal Catch-up Campaign) contained in the Schedule to these Directions.

Signed on behalf of the National Assembly for Wales

Dr Brian Gibbons

Date: 2006

Minister for Health and Social Services

SCHEDULE

The annex set out below is to be inserted after Annex H (Dispensary Services Quality Scheme) in the Directions to Local Health Boards as to the Statement of Financial Entitlements which came into force on 30 April 2005

“ANNEX I

PNEUMOCOCCAL AND HIB/MENC BOOSTER VACCINATIONS AND PNEUMOCOCCAL CATCH-UP CAMPAIGN

THE PROVISIONS SET OUT BELOW ARE THE PROVISIONS CONTAINED IN
WELSH HEALTH CIRCULAR (2006) 018 DATED 12 JULY 2006

WELSH HEALTH CIRCULAR



Llywodraeth Cynulliad Cymru
Welsh Assembly Government

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

Issue Date: 12th July 2006

Status: Action

- This guidance is new

Title: Changes to the Childhood Immunisation Programme

For Action by: See page 2

Action required: Yes

For Information to: See page 2

Sender: Neil Robins, Public Health Protection Division

Welsh Assembly Government contact(s) for policy queries only: Neil Robins (neil.robins@wales.gsi.gov.uk) on 029 2082 5397 or Matthew Thomas (matthew.thomas2@wales.gsi.gov.uk) on 029 2082 5410. Any queries about implementation need to be referred to the local NPHS Immunisation Co-ordinator.

Enclosure(s): Annex 1,2 and 3

Ffacs/Fax: 029 2082 5283

Minicom: 029 20823280

<http://howis.wales.nhs.uk/whcirculars.cfm>

| FOR ACTION TO: | | | FOR INFORMATION TO: | | |
|---|--|--|---|--------------------------------------|--|
| NPHS | Directors | | NHS | Director, Wales | |
| | Consultants in Communicable Disease | | | Regional Office Directors | |
| | Immunisation Co-ordinators | | | Regional Office Heads of Performance | |
| | Consultants in Pharmaceutical Public Health | | Chairman, All Wales Drug Contracting Committee | | |
| NHS | LHB | Chief Executives | All Wales Regional Specialist Pharmacist (Community Services) | | |
| | | Medical Directors | NHS Wales Direct | | |
| | | Nurse Directors | Medicines Information Centre | | |
| | | Finance Directors | LHB Prison Health Leads | | |
| | | Heads of Pharmacy & Medicines Management | HMP Health Leads | | |
| | | Trusts | Chief Executives | Wales Centre for Health | |
| | | Medical Directors | Head of Business Service Centres | | |
| | | Administrator Child Health System | | | |
| | | Chief Pharmacists | | | |
| | | Nurse Directors | | | |
| | | Occupational Health Departments | | | |
| | | Paediatric Consultants | | | |
| | Health Solutions Wales – Manager Child Health 2000 | | | | |
| | General Practice Managers | | | | |
| <ul style="list-style-type: none"> • • PLEASE ENSURE THAT THIS INFORMATION IS PASSED TO THE APPROPRIATE PEOPLE WITHIN YOUR COMMAND OR SPECIALISM | | | | | |

Changes to the Routine Childhood Immunisation Programme

1. Background to the changes

The background for the changes to the routine childhood immunisation programme is detailed in the CMO letter dated 8 February 2006. Further information is available on the website at www.immunisation.nhs.uk, and on the JCVI website (www.advisorybodies.doh.gov.uk/JCVI/). Additional information will be made available via factsheets and new green book chapters. Supporting information will also be available on HOWIS at <http://howis.wales.nhs.uk/immunisation>.

The changes to the routine schedule described below will be accompanied by a pneumococcal vaccination catch-up programme for children under two years of age at the start of the programme (Annex 1)

2. Timing

The routine programme will change on 4th September 2006. All children starting their immunisation from that date should be offered the new immunisation schedule. The Hib/MenC booster should also be introduced for children aged 12 months of age from that date.

In February our stated intention was to introduce these changes in the summer as soon as vaccine supply and other issues had been finalised. While some issues have taken longer to finalise than anticipated our aim remains to protect as many children as possible against pneumococcal disease before this year's seasonal winter peak in respiratory infection.

3. Routine Childhood Immunisation Schedule

| <i>When to immunise</i> | <i>What is given</i> | <i>Vaccine and how it is given</i> |
|---|---|---|
| Two months old | Diphtheria, tetanus, pertussis, polio and <i>Haemophilus influenzae</i> type b (DTaP/IPV/Hib) | One injection (Pediacef) |
| | Pneumococcal (PCV) | One injection (Prevenar) |
| Three months old | Diphtheria, tetanus, pertussis, polio and <i>Haemophilus influenzae</i> type b (DTaP/IPV/Hib) | One injection (Pediacef) |
| | Meningitis C (MenC) | One injection (Neisvac C or Meningtec) |
| Four months old | Diphtheria, tetanus, pertussis, polio and <i>Haemophilus influenzae</i> type b (DTaP/IPV/Hib) | One injection (Pediacef) |
| | Pneumococcal (PCV) | One injection (Prevenar) |
| | Meningitis C (MenC) | One injection (Neisvac C or Meningtec) |
| Around 12 months | <i>Haemophilus influenzae</i> type b, Meningitis C (Hib/MenC) | One injection (Menitorix) |
| Around 13 months | Measles, mumps and rubella (MMR) | One injection (Priorix or MMR II) |
| | Pneumococcal (PCV) | One injection (Prevenar) |
| Three years four months to five years old | Diphtheria, tetanus, pertussis and polio (dTaP/IPV or DTaP/IPV) | One injection (Infanrix-IPV or Repevax) |
| | Measles, mumps and rubella (MMR) | One injection (Priorix or MMR II) |
| Thirteen to 18 years old | Tetanus, diphtheria and polio (Td/IPV) | One injection (Revaxis) |

All children starting the immunisation programme at 2 months of age will follow the schedule listed in Table 1 (below):

Table 1

It is important that all those involved in immunisations are familiar with the childhood immunisation schedule. Changes are:

- the addition of a pneumococcal conjugate vaccine (PCV) at 2, 4 and 13 months of age
- one dose of MenC vaccine at 3 and at 4 months;
- a booster dose of Hib and MenC vaccine (given as a combined Hib/MenC vaccine) at 12 months of age.

Introducing these changes means that:

- infants will be offered different combinations of vaccines at their 2, 3 and 4 months visit.
- three injections will be offered to infants at 4 months of age.
- a new 12 month vaccination visit will be introduced

4. Children who are older than 2 months of age at the start of the new routine programme

There will be a small number of children who will be part-way through their primary vaccination schedule when the changes are introduced. It is important to ensure that these children receive three doses of DTaP/IPV/Hib (Pediacef), and at least two doses of MenC (with one dose being given at the 4 month visit).

All children, irrespective of their primary vaccination history, should receive a booster dose of Hib/MenC vaccine at their routine 12 months of age visit in order to ensure long-term protection. There is no Hib/MenC catch-up for children older than 12 months of age at the start of the new programme.

All children aged over 2 months and under 2 years of age at the start of the campaign will be offered PCV as part of the catch-up campaign (see Annex 1 for details).

5. Children at an increased risk of pneumococcal infection

Some groups of children are at increased risk from pneumococcal infection (see Table 2).

All at-risk children will routinely be offered PCV vaccine, according to the schedule for the routine immunisation programme (i.e. at 2, 4 and 13 months of age). In addition, all at-risk children should be offered a single dose of pneumococcal polysaccharide vaccine (PPV) when they are two years of age or over.

At-risk children presenting late for immunisation

At-risk children who present late for vaccination should be offered 2 doses of PCV¹ before the age of 12 months, and a further dose at 13 months of age. All at-risk children should also be offered a single dose of PPV when they are two years of age or older and at least 2 months after the final dose of PCV.

At-risk children aged from 12 months and under 5 years of age should be offered a single dose of PCV. However, please note that children in this age group who have asplenia or splenic dysfunction, or who are immunocompromised require a second dose of PCV because this group may have a sub-optimal immunological response to the first dose of vaccine. They should also be offered a single dose of PPV when they are two years of age or older (and at least 2 months after the final dose of PCV).

At-risk children presenting for immunisation aged 5 years and over should be offered a single dose of PPV.

6. Children under five years of age who have previously had invasive pneumococcal disease

All children aged under 5 years of age who have had invasive pneumococcal disease (IPD), for example pneumococcal meningitis or pneumococcal bacteraemia, should be offered a dose of PCV irrespective of previous vaccination history. Children under 13 months who are unvaccinated or partially vaccinated should complete the recommended immunisation schedule.

These children should be investigated for immunological risk factors to seek a possible treatable condition predisposing them to infection. If they are found to fall into one of the risk groups in Table 2, they should receive pneumococcal polysaccharide vaccine after two years of age (and at least 2 months after the final dose of PCV).

All cases of IPD in children eligible for routine PCV will be followed up by the Health Protection Agency (HPA). These cases will be offered antibody testing against each of the 7 vaccine serotypes and advice on clinical and immunological investigation (see http://www.hpa.org.uk/infections/topics_az/pneumococcal/guidelines.htm)

7. Vaccination of children with unknown or incomplete vaccination status

Where a child born in the UK presents with an inadequate or incomplete immunisation record, every effort should be made to clarify what they have had. A child who has not completed the routine programme for all vaccines should complete the course, including for pneumococcal vaccination. Children under 12 months of age require two doses of PCV, two months apart, followed by a dose at 13 months. Children aged from 12 to 23 months (i.e. up to 1 year 364 days) should be offered a single dose of PCV. Children aged 24 months (2 years) and over do not require vaccination.

Children coming to the UK may not have been offered pneumococcal vaccination previously. Where there is not a reliable history of previous immunisation it should be assumed they are unimmunised and the UK recommendation should be followed.

8. Pneumococcal Vaccination Catch-up Programme

Details of the pneumococcal catch-up programme for all children under two years of age are listed in Annex 1.

9. Pharmacy Issues

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

Pneumococcal Conjugate Vaccine (PCV)

PCV, brand name Prevenar™, is manufactured by Wyeth Pharmaceuticals.

Presentation

Prevenar is presented as a suspension for injection in a pre-filled syringe supplied in a ten syringe pack without needles. The pack size (10 doses) is 144mm x 100mm x 63mm.

During storage a white deposit and clear supernatant can be seen. The vaccine should be shaken well to obtain a homogeneous white suspension and should not be used if it contains any particulate matter once shaken or shows any variation in appearance.

¹ One month apart if necessary to ensure 2 doses are given before a dose at 13 months.

Dosage

A single dose of 0.5ml should be given at 2 months and 4 months followed by a third dose as a booster of 0.5ml at 13 months of age.

Administration

Vaccines are routinely given intramuscularly into the anterolateral thigh or upper arm (infants over 1 year of age). This is to reduce the risk of localised reactions, which are more common when the vaccine is given subcutaneously. For individuals with a bleeding disorder, however, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. The vaccine can be given at the same time as other vaccines such as DTaP/IPV/Hib, MenC and MMR but in a different site.

It is recommended that infants under 1 year of age should be given vaccinations in the anterolateral aspect of the thigh. Where two injections are given in the same thigh, they should be separated by at least 2.5 cm and a note should be made of which vaccine is given in which site. This should be recorded in the Personal Child Health Record (PCHR – red book) and the child's GP record.

The vaccine must not be mixed with other concurrently administered vaccines.

Hib-MenC Vaccine

Hib-MenC, brand name Menitorix™, is manufactured by GlaxoSmithKline.

Presentation

Menitorix is presented as a one-dose pack containing a vial of white powder and a 0.5ml pre-filled syringe containing a clear colourless liquid. It is supplied with two separate needles - a green needle (21g x 38 mm) for reconstitution and a blue needle (23g x 25 mm) for administration. The pack size (one dose) is 55mm x 133mm x 35mm.

Instructions for reconstitution of the vaccine are given at section 7 of the package leaflet.

Dosage

A single dose of 0.5ml is to be given as a booster at 12 months of age.

Administration

Vaccines are routinely given intramuscularly into the anterolateral thigh or upper arm. This is to reduce the risk of localised reactions, which are more common when the vaccine is given subcutaneously. For individuals with a bleeding disorder, however, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding.

Storage of vaccines

Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines are sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness cannot be guaranteed for vaccines unless they have been stored at the correct temperature. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

10. Reporting of adverse reactions

Prevenar and Menitorix both 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, pharmacist or parent suspects that any adverse reaction to Prevenar or Menitorix has occurred, it should be reported to the Commission on Human Medicines (CHM) using either the Yellow Card reporting form (e.g. in the BNF), the www.yellowcard.gov.uk website or by telephoning 0800 100 3352.

11. Vaccine Supply

There will be two 'allocated' deliveries of both pneumococcal vaccine (for routine use and catch-up) and Hib/MenC to each delivery point. The first supplies will be delivered in the period 7th – 18th August 2006. The second batch of supplies will be delivered in the period 4th – 15th September 2006. The amount of vaccine being sent to each delivery point has been calculated by tracking the previous usage of primary vaccines.

From 13th September 2006 onwards, further supplies should be ordered in the usual way from either Healthcare Logistics or local Trust pharmacies.

In North Wales, Healthcare Logistics will notify each delivery point of the quantity of their initial delivery and the date it will be delivered by letter prior to the initial delivery.

In all other parts of Wales, Trust pharmacies will receive an allocation from Healthcare Logistics and will arrange distribution to local GP surgeries.

Please hold any enquires to either Healthcare Logistics or your local Trust pharmacy regarding the new vaccines until contacted by them.

12. Vaccine Stock Management

Effective management of vaccines throughout the supply chain is an essential part of reducing wastage and maximising the efficiency of the programme. Even small reductions in vaccine wastage can have a major impact on vaccine supplies and their financing.

General practices are asked to carefully review current stocks of all vaccines and maintain levels of stock sufficient to last no more than 2 – 4 weeks. General practices with higher stocks of one or more vaccines should reduce stock holdings to the target level now, in preparation for the delivery of the new vaccines. Please ensure that any vaccines that are date expired are disposed of following local protocols. Excess supplies of vaccines within their shelf-life should be used before new supplies are ordered. General practices are asked to review their holdings of MenC vaccine in particular as the new routine programme only requires two doses of MenC vaccine.

The packaging of Prevenar is significantly larger than other vaccines currently being provided. Please ensure that sufficient fridge space is available for the new vaccines (see section 9 for pack size details).

13. Consumables

Please note that needles will need to be ordered to administer Prevenar. The following product is recommended:

FTRI163 blue needle 23g x 25 mm

These may be ordered through the NHS Logistics Authority in the usual way or for those requiring 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. Needles will not be supplied by Healthcare Logistics.

14. Child Health Systems

The introduction of the new routine immunisation schedule will have a significant impact on Child Health Systems. LHBs, surgeries, and health care professionals need to ensure that the child health system provider is familiar with the new routine schedule, and Immunisation co-ordinators may also assist in facilitating the new arrangements.

15. Patient Group Directions

As these children will be known at the time they attend the clinic for their vaccination, a Patient Specific Direction (PSD) will be required to cover vaccine administration. The PSD should contain sufficient information to ensure that patient safety is not compromised. The PSD may be developed using the PGD template issued as part of WHC 2000/116.

WHC 2000/116 is available from <http://howis.wales.nhs.uk/microsite/page.cfm?OrgID=295&PID=212>
Specimen PGDs will also be made available from <http://howis.wales.nhs.uk/immunisation>

16. Funding and Service Arrangements

NHS Employers has reached agreement with the BMA General Practitioners Committee and GPC (Wales). GPs will be remunerated £15.02 per child for the delivery of the pneumococcal vaccinations and the additional vaccination visit at 12 months to deliver the combined Hib and Men C vaccine. The Statement of Financial Entitlement will be amended and back dated to 4th September 2006.

Before the start of the programme an allocation from the Assembly Government will be made to each LHB for the additional costs incurred from implementing the revised programme. Additional details regarding this allocation will be sent to LHB and Trust Finance Directors shortly.

Separate funding arrangements are in place for the catch-up campaign (see Annex 1 section 10)

17. Consent

The changes to the vaccine programme will not affect the consent process: consent must be obtained before administration of all vaccines and is not brand specific.

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 benefits of the new vaccines, the possible side effects and how to treat them.

18. Information for parents and healthcare professionals

To support the new changes to the childhood immunisation schedule a range of bilingual information resources will be produced. New leaflets and factsheets for parents and healthcare professionals will be sent directly to GP surgeries, community pharmacists, child health departments, health promotion units and NHS Wales Direct before the start of the programme. These resources 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 the Welsh Assembly Government Publication Centre by e-mail: assembly-publications@wales.gsi.gov.uk or telephone: 029 2082 3683 (between 8.00am - 5.00pm, Monday – Friday). These resources will also be available to view and download from <http://www.cmo.wales.gov.uk/content/work/immunisation/leaflets-factsheets-e.htm>. The www.immunisation.nhs.uk website will be updated to reflect the changes to the programme, and a new section for Hib/MenC immunisation is being created. These new pages will go live at the time of the introduction of the new immunisation schedule.

TABLE 2 Pneumococcal Clinical Risk Groups for Children

Note: All children, including those in clinical risk groups, should be offered PCV according to the routine immunisation schedule. Children in the clinical risk groups listed below, aged 2 months to under 5 years of age should receive 7-valent pneumococcal conjugate vaccine (PCV) – as stated in Section 5 above. This should be followed by a single dose of 23-valent pneumococcal polysaccharide vaccine when they are 2 years of age or over (and at least two months after the last dose of PCV). Children over 5 years of age should receive a single dose of pneumococcal polysaccharide vaccine.

| (ii) Clinical risk group | <ul style="list-style-type: none"> <i>Examples (decision based on clinical judgement)</i> |
|---|---|
| Asplenia or dysfunction of the spleen | This includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction. |
| Chronic respiratory disease | This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neuromuscular disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below) is needed. |
| Chronic heart disease | This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure. |
| Chronic renal disease | This includes nephrotic syndrome, chronic renal failure, renal transplantation. |
| Chronic liver disease | This includes cirrhosis, biliary atresia, chronic hepatitis |
| Diabetes (requiring insulin or oral hypoglycaemic drugs) | This includes type 1 diabetes requiring insulin or type 2 diabetes requiring oral hypoglycaemic drugs. It does not include diabetes that is diet controlled. |
| Immunosuppression | <p>Due to disease or treatment, including asplenia or splenic dysfunction and HIV infection at all stages. Patients undergoing chemotherapy leading to immunosuppression. Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone 20mg or more per day (any age), or for children under 20kg, a dose of $\geq 1\text{mg/kg/day}$.</p> <p><i>Some immunocompromised patients may have a suboptimal immunological response to the vaccine.</i></p> |
| Individuals with cochlear implants | <i>It is important that immunisation does not delay the cochlear implantation.</i> Where possible, pneumococcal vaccination should be completed at least 2 weeks prior to surgery to allow a protective immune response to develop. In some cases it will not be possible to complete the course prior to surgery. In this instance, the course should be started at any time prior to or following surgery and completed according to the immunisation schedule. |
| Individuals with cerebrospinal fluid leaks | This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery. |

Annex 1

Pneumococcal Vaccination Catch-Up Programme

1. Timing of Pneumococcal Catch-Up Campaign

The pneumococcal catch-up campaign will start on 4th September. Our aim is to ensure all children in the target cohort are offered vaccination suitable for their age within 6 months of the start of the programme.

2. The Cohort

Children who will be over 2 months of age and under 2 years of age at the time of introduction will need to be invited to receive pneumococcal vaccine.

Children aged 2 months or under at the time of introduction will be offered pneumococcal vaccine as part of the new routine immunisation programme. Children 2 years of age or over at the time of introduction will not be part of the catch-up programme. The risk for children over 2 years of age becoming ill with pneumococcal infection is considerably less than in younger age groups. It is likely that pneumococcal infections in all age groups will fall as a result of introduction of the programme in the under two's.

3. The immunisations to be offered

The recommended schedule for implementing the programme is summarised in Annex 2. The child's date of birth runs down the left-hand side of the table, and the month in which the vaccine is recommended to be given runs along the top of the table.

In summary:

Children born between 05/09/04 and 03/08/05 (i.e. aged over 13 months of age and under 2 years at the start of the programme) should be offered one dose of PCV.

Children born between 04/08/05 and 03/02/06 (i.e. aged 8 months to 13 months of age at the start of the programme) should be offered one dose of PCV at their routine 13 month visit.

Children born between 04/02/06 and 03/07/06 (i.e. aged over two months and under 8 months of age at the start of the programme) should be offered two doses of PCV separated by a period of two months.

The following scenarios help to illustrate the use of the table:

A baby born on 21 June 2006 should be offered PCV at the routine 4 month visit in October, a second dose at an additional 6 month visit in December, and then a booster dose at the scheduled 13 month visit.

A child born 6 November 2005 should be offered PCV at the scheduled 13 month visit in December.

A child born on 2 April 2005 should be offered one dose of PCV in November¹.

A child born on 4 August 2004 is not eligible for the vaccine as they are over two years of age when the programme starts. Pneumococcal infections occur less frequently in children aged 2 years and over, and it is likely that pneumococcal infections in all age groups will fall as a result of introduction of the programme in the under two's.

A baby born on 17 July 2006 will not be part of the catch-up programme. This baby will receive pneumococcal vaccination as part of the routine programme.

4. Reporting of adverse reactions

Prevenar (and Menitorix) both 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, pharmacist or parent suspects that any adverse reaction to one of these vaccines has occurred, it should be reported to the Commission on Human Medicines (CHM) using the Yellow Card spontaneous reporting scheme (www.yellowcard.gov.uk).

¹ Please note that there are sufficient supplies of PCV vaccine for all children born between 05/09/04 and 03/08/05 to be offered PCV as soon as it is practically possible after the start of the programme. This will provide general practices with the flexibility to immunise eligible children over a shorter time period.

5. Vaccine Supply

There will be two 'allocated' deliveries of both pneumococcal vaccine (for routine use and catch-up) and Hib/MenC to each delivery point. The first supplies will be delivered in the period 7th – 18th August 2006. The second batch of supplies will be delivered in the period 4th – 15th September 2006. The amount of vaccine being sent to each delivery point has been calculated by tracking the previous usage of primary vaccines.

From 13th September 2006 onwards, further supplies should be ordered in the usual way from either Healthcare Logistics or local Trust pharmacies.

In North Wales, Healthcare Logistics will notify each delivery point of the quantity of their initial delivery and the date it will be delivered by letter prior to the initial delivery.

In all other parts of Wales, Trust pharmacies will receive an allocation from Healthcare Logistics and will arrange distribution to local GP surgeries.

Please hold any enquires to either Healthcare Logistics or your local Trust pharmacy regarding the new vaccines until contacted by them.

6. Vaccine Stock Management

Managing supplies of vaccine during the pneumococcal catch-up programme presents challenges in vaccine management with which health professionals are familiar. All staff ordering vaccines need to ensure that vaccine wastage is reduced as far as possible. Surgeries who find that they have excess pneumococcal vaccine remaining at the end of the catch-up programme should use it in the routine programme. Vaccine wastage for this catch-up programme should be negligible.

7. Consumables

Please note that needles will need to be ordered to administer Prevenar:

FTR163 blue needle 23g x 25 mm

These may be ordered through the NHS Logistics Authority in the usual way or for those requiring 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. Needles and syringes will not be supplied with the vaccine by Healthcare Logistics.

8. Child Health Systems

GPs and LHBs need to ensure that their child health system provider is familiar with the timing and role out of the catch-up programme. Immunisation co-ordinators may also assist in facilitating the new arrangements.

A draft letter is attached at Annex 3 for surgeries who send out their own appointments.

9. Patient Group Directions

As these children will be known at the time they attend the clinic for their vaccination, a Patient Specific Direction (PSD) will be required to cover vaccine administration.

The PSD should contain sufficient information to ensure that patient safety is not compromised. The PSD may be developed using the PGD template issued as part of WHC 2000/116.

WHC 2000/116 is available from <http://howis.wales.nhs.uk/microsite/page.cfm?OrgID=295&PID=212>
Specimen PGDs will also be made available from <http://howis.wales.nhs.uk/immunisation>

10. Funding and Service Arrangements for Catch-Up Campaign

The General Practitioners Committee of the British Medical Association, NHS Employers and GPC (Wales) have agreed to the introduction of the new vaccines and to the catch-up campaign.

An item of service payment of £7.51 per child has been agreed for practices administering this vaccine as part of the catch-up campaign. LHBs should therefore reimburse those practices who have been commissioned to provide this service a payment of £7.51 for each child immunised as part of this campaign.

LHBs should invoice the Welsh Assembly Government for reimbursement of the costs of claims from practices and also for the costs of vaccine used for the catch-up campaign. Send invoices FAO: Matthew Thomas, PHPD2, WAG, Cathays Park, Cardiff, CF10 3NQ.

11. Consent

The introduction of the pneumococcal catch-up programme will not affect the consent process: consent must be obtained before administration of all vaccines and is not brand specific.

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.

12. Information for parents and healthcare professionals

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 benefits of the new vaccines, the possible side effects, and how to treat them.

To support the pneumococcal catch-up programme a range of bilingual information resources have been produced. New leaflets and factsheets for parents and healthcare professionals will be sent directly to GP surgeries, community pharmacists, child health departments, health promotion units and NHS Wales Direct before the start of the programme. These resources 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 the Welsh Assembly Government Publication Centre by e-mail: assembly-publications@wales.gsi.gov.uk or telephone: 029 2082 3683 (between 8.00am - 5.00pm, Monday – Friday).

These resources will also be available to view and download from: <http://www.cmo.wales.gov.uk/content/work/immunisation/leaflets-factsheets-e.htm>

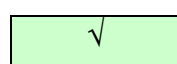
The www.immunisation.nhs.uk website will be updated to reflect the changes to the programme, and a new section for Hib/MenC immunisation is being created. These new pages will go live at the time of the introduction of the new immunisation schedule.

Annex 2

Pneumococcal Vaccination Catch-Up Table

| Recommended schedule for vaccination from 4 th September of the Pneumococcal catch-up programme 2006 | | | | | | | |
|---|-----------|---------|----------|----------|---------|----------|-------------------------------------|
| | September | October | November | December | January | February | |
| Child's date of birth at start of programme | | | | | | | Child's age at vaccination (months) |
| 5/09/04 to 3/11/04 | √ | | | | | | 23, 24 |
| 4/11/04 to 3/12/04 | √ | | | | | | 22 |
| 4/12/04 to 3/1/05 | | √ | | | | | 22 |
| 4/1/05 to 3/2/05 | | √ | | | | | 21 |
| 4/2/05 to 3/3/05 | | | √ | | | | 21 |
| 4/3/05 to 3/4/05 | | | √ | | | | 20 |
| 4/4/05 to 3/5/05 | | | | √ | | | 20 |
| 4/5/05 to 3/6/05 | | | | √ | | | 19 |
| 4/6/05 to 3/7/05 | | | | | √ | | 19 |
| 4/7/05 to 3/8/05 | | | | | √ | | 18 |
| 4/8/05 to 3/9/05 | √ | | | | | | 13 |
| 4/9/05 to 3/10/05 | | √ | | | | | 13 |
| 4/10/05 to 3/11/05 | | | √ | | | | 13 |
| 4/11/05 to 3/12/05 | | | | √ | | | 13 |
| 4/12/05 to 3/1/06 | | | | | √ | | 13 |
| 4/1/06 to 3/2/06 | | | | | | √ | 13 |
| 4/2/06 to 3/3/06* | | √ | | √ | | | 8, 10 |
| 4/3/06 to 3/4/06* | | √ | | √ | | | 7, 9 |
| 4/4/06 to 3/5/06* | √ | | √ | | | | 5, 7 |
| 4/5/06 to 3/6/06* | √ | | √ | | | | 4, 6 |
| 4/6/06 to 3/7/06* | | √ | | √ | | | 4, 6 |

Notes



Indicates the month in which the child should be offered PCV

*Children in this age group will receive a booster dose of PCV at 13 months of age and a dose of Hib/MenC at 12 months of age.

Please note that there are sufficient supplies of PCV vaccine for all children born between 5/09/04 and 3/8/05 to be offered PCV as soon as it is practically possible after the start of the programme. This will provide general practices with the flexibility to immunise eligible children over a shorter time period.

Annex 3

Suggested template letter of appointment for those practices sending out their own invitations for the pneumococcal catch-up programme

PRACTICE NAME

ADDRESS

[Date]

[Recipient's Address]

Dear Parent

The purpose of this letter is to inform you that your child needs a catch-up dose of pneumococcal conjugate vaccine (PCV). This vaccine has recently been introduced to the routine childhood immunisation programme and all children under two years of age are being offered protection. We are writing to invite you to bring your child for this vaccination on:

[date and time]

[venue]

This vaccination is important for your child. Pneumococcal disease is a particular risk in children under two years of age, and can lead to meningitis and septicaemia (blood poisoning). For more information about this vaccination, please read the leaflet (enclosed). If you have any further questions, please get in touch with your health visitor, practice nurse or GP.

As a practice we recommend pneumococcal conjugate vaccine for your child and hope that you will be able to bring your child for this appointment. If the above time and date is not suitable for you, please contact the surgery to arrange another appointment.

Yours sincerely

[Click here and type your name]

Senior Partner