AGREEMENT BETWEEN

DEPARTMENT OF HEALTH AND THE IRISH MEDICAL ORGANISATION IN RESPECT OF A CONTRACT BETWEEN HEALTH SERVICE EXECUTIVE(HSE) AND GENERAL PRACTITIONERS FOR THE DELIVERY OF THE PRIMARY CHILDHOOD IMMUNISATION PROGRAMME

(as amended and updated following the incorporation of the meningococcal C vaccine in October 2000, the Hib booster in September 2006, the inclusion of Hepatitis B and pneumococcal conjugate vaccine (PCV) to the schedule in July 2008, changes in retirement provisions with effect from 1/10/2009 and the establishment of the HSE to replace the former Health Boards in 2005).

AGREEMENT FOR THE DELIVERY OF THE PRIMARY CHILDHOOD IMMUNISATION PROGRAMME

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(hereafter called t	he "Contracting Medical Pr	actitioner"), having practice premises at
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		GMS Number
E Mail address		
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Signed:	(Signature of Medical	Practitioner)
Date:		
Home Address:		
Date of Birth:		
PPS Number:		
Signed:	Local Health Manager	Area
Date:		Aita
For office use only	:	
Contract From (a)	pproval date)	To
GMS Contract	□ Expiry Date	
GP No.	Vendor 1	No.

SCHEDULE

TERMS AND CONDITIONS OF AGREEMENT WITH REGISTERED MEDICAL PRACTITIONER.

1. SERVICE TO BE PROVIDED

- (a) The contracting general practitioner will deliver the primary immunisation programme outlined in Appendix 1 to this schedule.
- (b) With the childhood immunisations currently available it is possible to eradicate the diseases in question, if an uptake level of not less than 95% of the child population is achieved and maintained. The objective of the immunisation programme, therefore, is to achieve and maintain the required uptake of not less than 95% in the total child population for the childhood immunisation listed in Appendix 1.

2. MUTUAL OBLIGATIONS

2.1 Obligations of HSE

the administration and delivery of the immunisation programme. However, because the general practitioner is ideally placed to deliver the service the HSE is, under the terms of this contract, discharging their responsibility for the administration and delivery of the immunisation programmes by way of renewable contracts with general practitioners.

Nothing in this agreement shall be construed as preventing the HSE from making special arrangements where the uptake of immunisation among particular groups or in geographical areas is unacceptably low.

- (b) Subject to the provisions of section 7(e) below the HSE will offer a contract to all general practitioners in its area who wish to formally participate in the immunisation programme.
- (c) Each HSE Area will be responsible for achieving the national target in relation to immunisation in their areas. Contracting general practitioners will provide services for the HSE in accordance with the terms and conditions of this contract. The HSE will evaluate the operation of the contract and take appropriate action where it is found that any aspect of the contract is not being fulfilled.

2.2 <u>Immunisation Register</u>

- (a) Each HSE Area will be responsible for the compilation of an immunisation register from the birth notification forms.
- (b) The public health nurse, on her initial visit to the infant's home, will identify the contracting general practitioner whom the parent(s) agree to immunise their child. This information will be entered on the HSE's immunisation register. In general, medical card holders will be expected to attend their GMS doctor (that is if the GMS doctor has agreed to participate in the programme) for the immunisation of their child.
- (c) The HSE will notify the contracting general practitioner on a monthly basis of the children who should be immunised and at the same time invite

parents to attend the contracting general practitioner for the immunisation of their child. This notification to the general practitioner will be regarded as the "registration" for the purposes of the payments mechanism set out in section 6 below.

2.3 Obligations of contracting general practitioners

- (a) Contracting general practitioners in the immunisation programme will be responsible for ensuring that, as far as possible, there is an uptake level of not less than 95% among the children assigned to them. They will be fully accountable to the HSE Area with whom they have the formal agreement, for identifying promptly the children who have been immunised and those who have not.
- (b) Contracting general practitioners will be required to take an appropriate history, provide pre-immunisation advice and information and examine the child. The consent of the parent must also be obtained in the form of Appendix 2/3.
- (c) In addition contracting general practitioners will keep a record of the child's immunisation and this will include:-
 - The name, address and date of birth of the child
 - The dates on which each immunisation was administered
 - The name of the vaccine administered
 - The name of the manufacturer of the vaccine
 - The batch number from which the particular vaccine came

- The dosage administered in respect of each vaccine and site
- Any adverse reactions and the site thereof, (which should be reported to the Irish Medicines Board and to the HSE).
- The name of the doctor administering the vaccine
- Recording of parent's refusal to have a child immunised, and the reasons therefore
- (d) These records must be kept indefinitely and must also be available to the HSE and/or to the Department of Health & Children as required.
- (e) Contracting general practitioners will be expected to participate in continuing Medical Education programmes as shall be necessary to update their knowledge about current immunisations.
- (f) Contracting general practitioners have a responsibility for the continuing updating of their knowledge about current immunisations. The HSE will facilitate general practitioners in obtaining this knowledge as appropriate.

Contracting general practitioners will be expected to promote the recommended childhood immunisations to parents. The Department of Health & Children and the HSE will be responsible for promotion on a population basis and will assist general practitioners as appropriate in this regard.

2.4 <u>Notification of Immunisation to the HSE</u>

- The contracting general practitioner will notify the HSE not later than the seventh working day of each month of the children who have been immunised to facilitate routine monitoring of uptake and in particular to identify children who have not been immunised (See also 2.5). The contracting general practitioner's return should contain the type of information outlined in the sample 'Primary Childhood Immunisation Record/Return Forms' (see Appendices 3) the white copy of which will be retained by the general practitioner for his/her own records.
- (b) The HSE Areas will notify each contracting general practitioner of the success rate, including details of those immunised, in the cohort of children assigned to him/her and of the level of uptake in the community care area and in the HSE region.

2.5 Identification and follow up of children who have not been immunised

(a) Where parent(s) do not respond to the invitation within one month of the due date to have their child immunised, the contracting general practitioner will contact the parent(s), by way of letter on the lines set out in Appendix 4, to advise, encourage and urge them to immunise their child.

The contracting general practitioner will also take all practicable further steps, which should be noted in each case, to achieve immunisation. Where appropriate, such steps may include contact with the parent(s), availing of any opportunity to discuss the matter with the parent(s), which might arise through surgery or domiciliary visits for other purposes and liaison with the public health nurse. Where these and any other measures taken by the general practitioner fail to achieve immunisation within two months of the due date to have the child immunised, the general practitioner will notify the HSE. Where the parent's declared intent is not to immunise, this declaration preferable in writing should be noted, kept on file and made

known to the HSE On receipt of information on the children who have not been immunised the HSE will make immediate and appropriate follow up arrangements. This would include a visit by the public health nurse to the family to discuss with and encourage the parent(s) to have their child immunised by the general practitioner. Where all reasonable measures have failed to achieve immunisation, parent(s) who have not already done so should be asked by the HSE to declare in writing their intent in relation to immunisation. In such cases the child will not be included in the calculation of the uptake levels as detailed in 2.6 below.

2.6 Uptake levels

- (a) For contractual purpose "uptake levels" will be calculated for each calendar year in respect of the cohort of children, on the contracting general practitioner's panel who reach their second birthday during that year, but excluding children whose parent(s) have refused immunisation, whose families have moved, children who have died or where immunisation is contraindicated. Where in any calendar year, 95% of this cohort, adjusted as above, had completed the course of immunisation by the time of their second birthday; the contracting general practitioner will qualify for the bonus payment which is set out in section 6 below.
- (b) The details of children who receive less than the recommended number of doses and/or who are immunised later than 2 years should also be recorded by the contracting general practitioner and notified to the HSE.
- Every effort should be made to ensure that all children are immunised, even if they are older than the recommended age-range and that no opportunity to immunise should be missed in the interests of public health. Payment in respect of these immunisations will be on a pro rata basis.

3 <u>CONTRAINDICATIONS</u>

In order to ensure that consistent advice is given to parents, all health professionals should be aware that there are very few contraindications to the recommended childhood immunisations. Extracts from the Immunisation Guidelines for Ireland, 2008 Edition are included in Appendices 5. Where a general practitioner has any doubt, appropriate advice should be sought from a Consultant Paediatrician, the appropriate medical staff of the HSE or other appropriate health professional.

4 IMMUNISATION RECORD CARD

An immunisation record card containing the type of information outlined in the sample forms in Appendices 6 will be provided for use by contracting general practitioners and parents to record the child's immunisation. The objectives of the record card, which will be held by the parents, are to provide parents with readily accessible information on the immunisation status of their child and to provide evidence of immunisation as and when required.

5 STORAGE AND DISPOSAL OF VACCINES

An integral part of a quality immunisation service is the availability of a safe and efficacious vaccine. The procedures which must be adhered to, towards ensuring and maintaining the safety and efficacy required, are outlined in Appendix 7. (See also "A Practical Guide to Immunisation 2008", Published by HSE National Immunisation Office). The HSE National Immunisation Office will undertake to ensure the maintenance of the Cold Chain in the delivery of all vaccines to all GPs. The contracting general practitioner must ensure that the cold chain in maintained from the time that the vaccine is received by him/her to the immunisation of the child.

6 CLAIMS/PAYMENT

(a) The contracting general practitioner will be entitled to payment for giving primary childhood immunisations on the following basis on rates approved

by the Minister from time to time following consultation with the Minister and the Irish Medical Organisation. The following is agreed from 1/9/08:

- (i) \notin 40.84 following registration of the child (see 2.2(c))
- (ii) €136.07 in respect of those children born up to 30/06/08 who have received complete courses of immunisation against DTaP, Hib, Polio (5 in 1), Meningococcal C and MMR (given from 12 months of age). This amount will be paid by the HSE on receipt of notification of completion of the complete course of immunisation against DTaP, Hib, Polio and Meningococcal C. €136.07 + 62.55 in respect of those children born on or after 01/07/08 who have received complete courses of immunisations against DTaP, Hib, Polio, Hep B (6 in 1), Meningococcal C (Dose 3 given from 12 months of age), PCV (Dose 3 given from 12 months of age), and MMR (given from 12 months of age).
- (iii) For children who have started or completed the primary immunisation a payment of €38.95 will be paid for the Meningococcal C "Catch Up" programme.
- (iv) For children who receive a Hib booster from 12 months of age, a payment of €20.85 will be made. (The Hib booster is not required if a child received 5 in 1 or 6n1 after 12 months of age and therefore no payment will be due).

Where the MMR is not administered by the contracting general practitioner on whose list the child is registered, a pro-rata deduction will be made from monies due to the contracting general practitioner.

Where the complete course of immunisation is not administered, pro-rata payments will be made.

Similarly, where another contracting general practitioner immunises a child who is not on his register or where a child, who is not considered to be part of the target group (e.g. an older child as outlined in 2.6 (c)), is immunised by a contracting general practitioner, pro-rata payments will be made.

- (v) Where the contracting general practitioner has achieved the 95% uptake level as defined in section 2.6 (a), a bonus of €65.55 will be paid in respect of each child on the panel who has reached his/her second birthday in the calculation period.
- **(b)** Payments will be processed and made by the HSE Area's:-
 - I. Within 1 month of registration.
 - II. Within 1 month of receipt of notice of completing course of immunisation
 - III. Within 3 months following the calendar year in which uptake levels are calculated.
- (c) The contracting general practitioner will not be entitled to accept any other payment or any fee or remuneration in respect of immunisation which can be provided under this agreement. Any further consultation in relation to a vaccination will, however, be covered by the GMS or subject to a private surgery fee.

7. <u>DISPUTES AND TERMINATION</u>

(a) Either party may terminate this agreement by giving not less than three months notice to the other party.

where the CEO has reason to believe that the contracting general practitioner has not complied with any of the terms of the agreement, s/he shall notify the contracting general practitioner by registered post of the reasons for such belief. The CEO or his/her representative and the contracting general practitioner will meet within 21 days of the issue of the notification, at which time the general practitioner shall respond to the claims made by the CEO. The general practitioner may also, where applicable, be accompanied by a representative of the IMO at this meeting. If, following this meeting, the CEO is satisfied that the general practitioner has not complied with the terms of the agreement or has failed to deliver the immunisation programme, the CEO shall:

Issue a warning to the contracting general practitioner. This warning shall be in place for 6 months. At the expiry of this 6 month period, if the general practitioner has complied fully with the terms of the agreement, the warning shall be struck from the general practitioner's record.

(c) Where the general practitioner has been issued with a warning by the CEO and where s/he, during the 6 months following the warning, fails to comply with the terms of the agreement then the CEO shall as s/he thinks fit:

Require the contracting general practitioner to pay to the HSE a monetary penalty which shall be recoverable by reduction from any monies payable under this contract or as a simple contract debt.

Or

Terminate the agreement.

- (d) In the case of a serious breach of the agreement, the CEO may give notice of termination of the agreement or other disciplinary action. Such notice shall specify a date not earlier than 21 days from the date of its issue before which the decision may be appealed. Except in cases where the patients may be placed in jeopardy, a notice of termination shall not provide for suspension.
- Where the CEO is satisfied that the care of patients is placed in jeopardy, s/he may decline to offer the contract or in the case of a contract holder may suspend the operation of a general practitioner's agreement with immediate effect pending investigation of the matter. When the operation of an agreement with a contracting general practitioner has been suspended, the CEO shall give notice of termination of the agreement or other disciplinary action and the Tribunal referred to in Paragraph 7 (g) shall in all cases meet to consider the notice of termination or other disciplinary action, not later than 21 days from the date of the suspension
- (f) A decision, not to offer a contract, to terminate the contract or to impose other disciplinary action under 7 (c) or (d) may be appealed by the applicant or contracting general practitioner to the Tribunal referred to in paragraph 7 (g) to be established for the purpose in which case the relevant decision of the CEO shall not take effect unless and until such decision is upheld by the Tribunal.
- (g) The Tribunal which will be set up by the CEO shall consist of one person nominated by the Irish Medical Organisation, one person nominated by the CEO and an independent chairperson who is acceptable to the Irish Medical Organisation and the CEO. This Tribunal shall have power only in relation to matters arising from action taken under this section of this agreement.

Where the Tribunal finds that the decision not to offer a contract or disciplinary action/termination of the contract would be unfair it shall recommend the withdrawal of the decision of the CEO. The CEO shall comply with the finding of the Tribunal. The Tribunal may uphold the decision of the CEO or recommend disciplinary action other than that imposed by the CEO, where they confirm a series breach of the agreement.

- (h) This contract shall be terminated where the contracting general practitioner's name is erased from the register of medical practitioners under the Medical Practitioners Act, 1978, or where an order is made by the High Court that the name of the contracting general practitioner shall not have effect in the general register of medical practitioners, the contract shall be suspended for such period as may be specified in such order.
- (i) This contract shall be terminated, on such notice not exceeding three months as may be agreed to by the CEO, upon the general practitioner accepting employment in a whole time capacity in the service of the state or of the HSE or otherwise.
- The CEO may terminate the agreement where the HSE is satisfied, after compliance with procedures analogous to those contained in Circular 13/75 determined by the Minister for Health & Children in agreement with the Irish Medical Organisation, that the contracting general practitioner is suffering from permanent infirmity of mind or body. An appeal shall lie to the Minister for Health & Children against a decision of the HSE to terminate the agreement under this paragraph and the HSE shall comply with any direction in that respect given by the Minister for Health & Children.

(k) The agreement shall terminate on the contracting general practitioner reaching the age of 70 years except that where a contracting general practitioner has a GMS contract, this agreement will terminate when s/he reaches the age at which the GMS contract terminates. The contracting general practitioner shall, on entering into agreement, furnish evidence of his date of birth.

8 GENERAL

- (a) This contract will be reviewed from time to time by the Minister, the HSE and the Irish Medical Organisation.
- (b) This arrangement will not preclude further negotiations between the parties taking place prior to immunisation services developments, including any legislative provisions, which may arise from time to time.

TIMETABLE FOR IMMUNISATION

Appendix 1

(To be given by General Practitioners)

Age of Child	For children born before 1/7/08	For children born on or after 1/7/08
At 2 months	Diphtheria) Tetanus) Acellular Pertussis) 5 in 1 Hib) Polio (IPV)) + Meningococcal C	Diphtheria) Tetanus) Acellular Pertussis) 6 in 1 Hib) Polio (IPV)) Hep B) + Pneumococcal (PCV)
At 4 months	Diphtheria) Tetanus) Acellular Pertussis) 5 in 1 Hib) Polio (IPV)) + Meningococcal C	Diphtheria) Tetanus) Acellular Pertussis) 6 in 1 Hib) Polio (IPV)) Hep B) + Meningococcal C
At 6 months	Diphtheria) Tetanus) Acellular Pertussis) 5 in 1 Hib) Polio (IPV)) + Meningococcal C	Diphtheria) Tetanus) Acellular Pertussis) 6 in 1 Hib) Polio (IPV)) Hep B) + Pneumococcal (PCV) + Meningococcal C
At 12 months	Measles) Mumps) MMR Rubella) + Hib	Measles) Mumps) MMR Rubella) + Pneumococcal (PCV)
At 13 months		Meningococcal C + Hib

For vaccination of late entrants to Irish Health Care System please refer to pages 13, 14, and 15 in the Immunisation Guidelines for Ireland, 2008 Edition

Primary Childhood Immunisation Programme

I consent to have my child (Name)	
Address	
Date of Birth	
Immunised against: -	
FOR CHILDREN BORN BEFORE 1/7/08 Diphtheria//Tetanus/Pertussis (DTaP)	
Polio (IPV) Haemophilus Influenza (Hib)) 5 i	n 1
+	
Meningococcal C	
OR –	
FOR CHILDREN BORN ON OR AFTER 1/7/2 Diphtheria//Tetanus/Pertussis (DTaP) Polio (IPV), Haemophilus Influenza (Hib),	008
Hepatitis B.	6 in 1.
+	
Meningococcal C	
+ Pneumococcal (PCV)	
I have been made aware by my medical practiti possible adverse reactions to these immunisation	
Signed:	
Date:	

APPENDIX 2A

Primary Childhood Immunisation Programme

I consent to have my child (Name)
Address
Date of Birth
Immunised against:- (Tick boxes √ as necessary)
Measles Mumps Rubella (MMR)
I have been made aware by my medical practitioner of the small risk of possible adverse reactions to these immunisations.
Signed:
Date:

GP Record/Return Form for use with children Born Before 1/7/08

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GP IMMUNISATION RECORD/RETURN FORM 1 (For children born from 1^{st} July 2008)

Appendix 3

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GP IMMUNISATION RECORD/RETURN FORM 2

Appendix 3

(For children born from 1st July 2008)

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Dear

I note from my records that you have not responded to the HSE's invitation to attend my surgery for the immunisation of your child.

I would like to advise you of the importance of immunisation. Immunisation protects your child against diseases that can cause serious illness and even death. By protecting your child you also protect your family and the whole community from a number of serious diseases. It is very important that your child is immunised now. Please attend for your child's immunisation as soon as possible.

If you are in anyway concerned about immunisation please come and see me and we can discuss the matter.

Yours sincerely

Dr General Practitioner

CONTRAINDICATIONS AND PRECAUTIONS TO VACCINES

- Minor illness with a temperature of less than 38oC is not a reason to defer immunisation.
- Sometimes these recommendations differ from those in licensed information on the Summary of Product Characteristics (SPC).
- The benefits and risks of giving specific vaccines should be carefully considered when the events listed as precautions exist.
- When there are doubts as to whether or not to give a vaccine contact a Paediatrician or Public Health Specialist.

Table 2.4 Contraindications and precautions for specific vaccines

Vaccine	Contraindications	Precautions
General for all vaccines	Confirmed anaphylactic reaction to the vaccine or to a constituent. (See introduction in Immunisation guidelines of Ireland 2008 Edition.)	Moderate or severe illness; defer until recovery, unless the benefits outweigh the risks. Latex allergy (see note 2 below)
DTP/DTaP/Tdap (see note 1 below)	As above (see note 1 below)	Evolving neurological conditions; defer until stable.
IPV	As above	Pregnancy; give if benefits outweigh risks.
MMR	As above Pregnancy	-Recent administration of blood or blood product (defer for at least 3 months) -Immune deficiency or suppression -Thrombocytopenia within 6 weeks of a previous dose (see Chapter 8)

Notes

- 1. Encephalopathy, temp >40.5°C, seizures, prolonged crying or hypotonic-hyporesponsive episodes following a previous dose of a whole-cell pertussis-containing vaccine have <u>not</u> been shown to result in permanent damage, are far less likely to occur following acellular pertussis vaccines, and **are no longer regarded as either precautions or contraindications.**
- 2. Vaccines supplied in vials or syringes containing rubber should not be used in those who had an anaphylactic reaction to latex.

(Immunisation Guidelines for Ireland, 2008 Edition, Page 18, Chapter 2)

Conditions which are NOT contraindications to immunisation

- 1. Family history of any adverse reactions following immunisation.
- **2.** Minor infections without fever or systemic upset.
- 3. Family or personal history of convulsions. Antipyretic measures are advisable following immunisation of children under five years with a family history of febrile convulsions.

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- **4.** History of pertussis, measles, rubella or mumps infection in the absence of proof of immunity.
- 5. Prematurity or low birth weight (defer Hep B in those under 2 kg unless there is a maternal history of HBV infection).
- **6.** Stable neurological conditions e.g. cerebral palsy.
- 7. Recent contact with an infectious disease.
- **8.** Asthma, eczema, hay fever, migraine or food allergy.
- **9.** Therapy with antibiotics or low dose oral or locally-acting steroids.
- **10.** Child's mother is pregnant.
- 11. Child being breastfed.
- **12.** History of jaundice.
- 13. Child over the age recommended in immunisation schedule.
- **14.** Recent or imminent surgery or general anaesthesia.
- **15.** Corticosteroid replacement therapy.

Taken from Immunisation Guidelines for Ireland, 2008 Edition, page 17.

Vaccination of those who are HIV positive (Table 2.5)1

Vaccine	Asymptomatic HIV Infection	Symptomatic HIV Infection
Diphtheria, tetanus,	Yes	Yes
pertusis,polio		
MMR	Yes	Yes
Haemophilus	Yes	Yes
Meningococcal	Yes	Yes
Pneumococcal (PPV, PCV)	Yes	Yes
Influenza	Yes	Yes
Hepatitis A and B	Yes	Yes
Varicella	Yes	Yes if CD4 >25%
BCG ²	No	No
OPV	No	No
Yellow Fever	No	No

¹ Page 24, Immunisation Guidelines for Ireland 2008 Edition

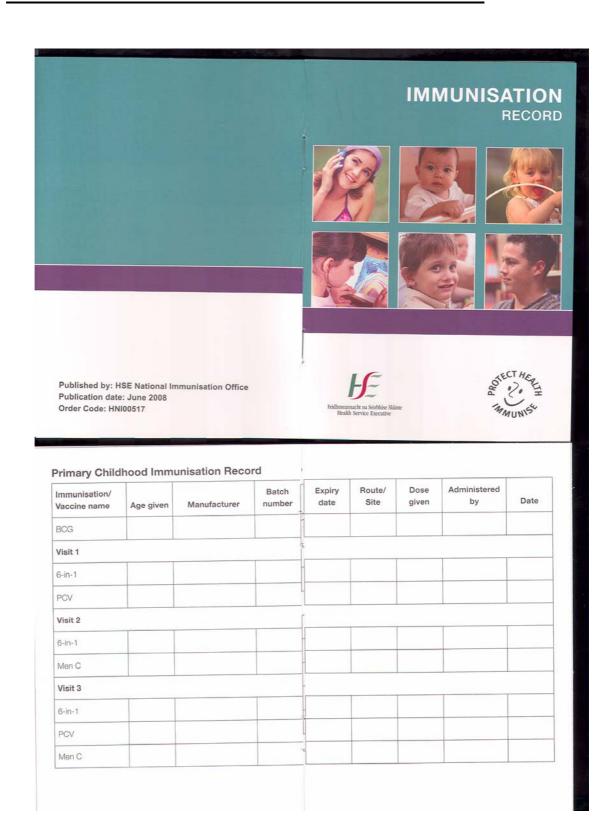
² See Chapter 16 re HIV and BCG in Immunisation Guidelines for Ireland 2008 Edition

Sample Immunisation Record page for children born before 1/7/08

	me umetable for i	mmun	iisation as r	evised from	Octobe	r 2002
ge	Immunisation		Batch No.	Date Given	Initials	Comments (if any)
	: BCG (usually in maternity ho	spitals)				T
At 2 months:	Diphtheria Tetanus Whooping Cough* Hib Inactivated Polio Meningococcal C	5 in 1				
At 4 months:	Diphtheria Tetanus Whooping Cough* Hib Inactivated Polio	5 in 1				
At 6 months:	Meningococcal C Diphtheria Tetanus Whooping Cough* Hib Inactivated Polio	5 in 1				
At 12-15	Meningococcal C Measles			-	-	
months:	Mumps Rubelia	MMR				
r 4-5 years:	Hib Diphtheria Whooping Cough* Tetanus Inactivated Polio Vaccine Measles Mumps Rubelia	4 in 1				
11-12 years:	Measles Mumos Rubelia	MMR				
	ious doses have been given)					
10-14 years:	BCG' (interval of 4 weeks after MMR)		-			
r 11-14 years:	Tetanus Diphtheria (low dose)	н				

From Child Health Record booklet - Health Promotion Unit

Immunisation Record booklet for children born from 1/7/08



1. STORAGE AND DISPOSAL OF VACCINES

As indicated in section 5 of the Schedule an integral part of a quality immunisation service is the availability of a safe and efficacious vaccine. It is recommended that the following procedures be adhered to towards ensuring and maintaining the safety and efficacy required.

2. PRELIMINARY POINTS

- (i) The leaflets supplied with the produce and prepared by the Manufacturer in consultation with the Irish Medicines Board should be read by the professional administering the vaccine.
- (ii) The identity of the vaccine must be checked to ensure the right Product is used in the appropriate way on every occasion.
- (iii) The expiry date must be noted.
- (iv) The date of immunisation, name of vaccine and batch number must be recorded on the child's record. When two vaccines are given simultaneously, the relevant sites should be recorded to allow any reactions to be related to the causative vaccine.
- (v) The recommended storage conditions must have been observed.

3. RECONSTITUTION OF VACCINE

- (i) Freeze dried vaccines must be reconstituted with the diluent supplied and used within the recommended period after reconstitution.
- (ii) Before injection the colour of the product must be checked with that stated by the manufacturer in the package insert. The diluent should be added slowly to avoid frothing. A sterile syringe with a 21G needle should be used for reconstituting the vaccine, and a small gauge needle for injection.

4. STORAGE AND DISPOSAL

(i) Manufacturers' recommendations on storage must be observed and care should be taken to ensure that, on receipt, vaccines are immediately placed under the required storage conditions. Vaccines must not be kept at temperatures below 0° as freezing can cause the deterioration of the vaccine and breakage of the

- container. The shelf immediately below the icebox should not be used for the storage of vaccines.
- (ii) A maximum/minimum thermometer should be used in refrigerators where vaccines are stored, irrespective of whether the refrigerator incorporates a temperature indicator dial.
- (iii) Special care should be taken during defrosting the refrigerator to ensure that the temperature of the vaccines does not exceed the specified range for the periods of time specified by the vaccine manufacturer. An alternative refrigerator or insulated containers should be used for vaccine.
- (iv) Reconstituted vaccine must be used within the recommended period, varying from one to four hours, according to the manufacturer's instructions. Single dose vials are preferable; once opened, multi-dose vials must not be kept after the end of the session and any vaccine left unused must be discarded.
- (v) The distribution of vaccines should be in accordance with the recognised guidelines on good distribution practice wholesaling of medicinal products.
- (vi) Unused vaccine should be returned via the National Cold Chain delivery service for disposal.

Additional information available in "A Practical Guide to Immunisation". Published by the: National Immunisation Office (2008).

REFERENCES

Immunisation Guidelines for Ireland, 2008 Edition.

Royal College of Physicians of Ireland & National Immunisation Advisory Committee.

A Practical Guide to Immunisation.

Published by the HSE National Immunisation Office (NIO), April 2008.

Information Pack on the New Childhood Immunisation Schedule.

Published by the HSE National Immunisation Office (NIO), June 2008

USEFUL WEBSITES FOR UP TO DATE INFORMATION ON IMMUNISATIONS

www.immunisation.ie

www.rcpi.ie

www.hspc.ie

www.immunisation.nhs.uk

www.cdc.gov

www.dohc.ie