

<b>MODEL STANDING DRUG ORDER (SDO)</b>	
<b>Title</b>	<b>H1N1 2009 Influenza Vaccine Panvax and Panvax Junior</b>
<b>Location</b>	www.health.sa.gov.au/pehs/immunisation-index.htm
<b>Date</b>	December 2009
<b>Due date for renewal</b>	30 June 2010
<b>Author</b>	Immunisation Section (IS)
<b>Person Responsible</b>	Maureen Watson
<b>Position</b>	Nursing Director
<b>References</b>	<ol style="list-style-type: none"> <li>1. NHMRC <i>The Australian Immunisation Handbook</i> 9th Edition 2008</li> <li>2. Product Information</li> <li>3. Nursing and Midwifery Practice Act 2008</li> <li>4. Controlled Substances Act 1984 (and its Regulations)</li> <li>5. South Australian Medical Practice Act 2004</li> <li>6. Consent to Medical Treatment and Palliative Care Act 1995</li> <li>7. <u>Delegation by a Registered Nurse or Midwife to an Unlicensed Healthcare Worker (May 2005, amended August 2009)</u></li> </ol>
<b>APPLICATION OF MODEL STANDING DRUG ORDER</b>	
<b>1. Clinical practice areas where SDO can be used</b>	Any immunisation service conducted by a Medical Practice, Local Government, Community Health Centre, Hospital, Aboriginal Health Service, Royal Flying Doctor Service or any other health service
<b>STAFF AUTHORISATION</b>	
<b>2. Staff credentialing requirements</b>	<p><b>2.1 Registered Nurse</b></p> <ol style="list-style-type: none"> <li>2.1.1 Accountable and responsible for own actions within nursing practice (Australian Nursing and Midwifery Council (ANMC) 2006 National Competency Standards)</li> <li>2.1.2 Practices in accordance with the Nurses Board 'Standard for Medication Management'</li> <li>2.1.3 Current Certificate of Registration with the Nursing and Midwifery Board of SA</li> <li>2.1.4 Certificate in Cardio Pulmonary Resuscitation (CPR) within the last 12 months</li> </ol> <p><b>2.2 Enrolled Nurse</b> <i>Can immunise if they can demonstrate all of the following:</i></p> <ol style="list-style-type: none"> <li>2.2.1 Competence to practice</li> <li>2.2.2 Compliance with organisational standards, policies and procedures</li> <li>2.2.3 Compliance with all relevant legislation and guidelines</li> <li>2.2.4 Practices in accordance with the Nursing and Midwifery Boards 'Standard for Medication Management'</li> <li>2.2.5 Assessment of the client by Registered Nurse or Medical Practitioner prior to vaccination</li> <li>2.2.6 Direct or indirect supervision by a Registered Nurse</li> <li>2.2.7 Current Certificate of Enrolment with the Nursing and Midwifery Board of SA</li> <li>2.2.8 Certificate in CPR within the last 12 months</li> </ol> <p><b>2.3 Aboriginal Health Workers</b> <i>Can immunise if they can demonstrate all of the following:</i></p> <ol style="list-style-type: none"> <li>2.3.1 Have received delegation from a Registered Nurse or</li> </ol>

	<p>Midwife</p> <p>2.3.2 Competence to practice</p> <p>2.3.3 Compliance with organisational standards, policies and procedures</p> <p>2.3.4 Compliance with all relevant legislation and guidelines</p> <p>2.3.6 Assessment of the client by Registered Nurse or Midwife prior to vaccination</p> <p>2.3.7 Direct or indirect supervision by a Registered Nurse</p> <p>2.3.8 Certificate in CPR within the last 12 months</p>
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**H1N1 2009 Influenza ~ MODEL STANDING DRUG ORDER**

<b>3. Background</b>	<p><b>3.1</b> This model Standing Drug Order (SDO) will not meet the needs of all cases and <b>must always be used</b> in conjunction with the Product Information and the current Australian Immunisation Handbook</p> <p><b>3.2 Clinical assessment and advice from a Medical Practitioner</b> should be sought if the recommendations for a specific clinical situation cannot be determined when using the SDO together with the Product Information and the Australian Immunisation Handbook.</p>																
<b>4. Purpose and scope</b>	<b>4.1</b> To ensure the correct and controlled administration of Panvax <sup>®</sup> and Panvax Junior <sup>®</sup> , the H1N1 2009 <b>influenza</b> vaccine by a person authorised according to the criteria in this Standing Drug Order policy																
<b>5. Precautions</b>	<p><b>5.1 NOT</b> to be administered with the drawing up needle</p> <p><b>5.2 NOT</b> to be mixed with other vaccines in the same syringe</p> <p><b>5.3 NOT</b> to be administered intravenously or intradermally</p> <p><b>5.3</b> Use with caution in patients on warfarin, theophylline, phenytoin, phenobarbitone or carbamazepine.</p> <p><b>5.4</b> If Guillain-Barré Syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give Panvax<sup>®</sup> H1N1 vaccine should be based on careful consideration of the potential benefits and risks.</p>																
<b>6. Indications for Use</b>	Panvax <sup>®</sup> H1N1 Influenza vaccination is recommended for anyone from 6 months of age who would like to prevent influenza disease caused by the influenza A (H1N1) 2009 virus.																
<b>7. Dosage</b>	<p>Infants 6 months to 3 years of age – 0.25mL</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose</th> <th>Vaccine Presentation</th> <th>Number of doses (1<sup>st</sup> year of Vaccination)</th> </tr> </thead> <tbody> <tr> <td>6 months – &lt; 3 years</td> <td>0.25ml</td> <td>Pre-filled syringe</td> <td>2* doses at least 4 weeks apart</td> </tr> <tr> <td>3-9 years</td> <td>0.5ml</td> <td>Multi-dose vial</td> <td>2* doses at least 4 weeks apart</td> </tr> <tr> <td>&gt;10 years</td> <td>0.5mL</td> <td>Multi-dose vial</td> <td>1 dose</td> </tr> </tbody> </table>	Age	Dose	Vaccine Presentation	Number of doses (1 <sup>st</sup> year of Vaccination)	6 months – < 3 years	0.25ml	Pre-filled syringe	2* doses at least 4 weeks apart	3-9 years	0.5ml	Multi-dose vial	2* doses at least 4 weeks apart	>10 years	0.5mL	Multi-dose vial	1 dose
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<p><b>8. Limitations</b></p>	<p><b>8.1</b> Infants and elderly persons with impaired immunity may develop lower post-vaccination antibody titres.</p> <p><b>8.2</b> Persons who are immunocompromised or are undergoing corticosteroid or immunosuppressant therapy may have a lower antibody response.</p>
<p><b>9. Relevance to other SDO policies</b></p>	<p><b>9.1</b> Panvax<sup>®</sup> or Panvax Junior<sup>®</sup> H1N1 vaccine can be given at the same time as other childhood vaccines but at a different site and in separate syringes.</p> <p><b>9.2 Adrenaline must always be readily available</b> Refer to the 'Adrenaline' SDO</p>
<p><b>10. Contra-indications</b></p>	<p><b>10.1</b> Anaphylaxis following a previous dose of a seasonal influenza vaccine, or to eggs, chicken protein, thiomersal (Panvax Junior is thiomersal free), neomycin, polymyxin B sulfate or any components of the vaccine</p> <p><b>10.2</b> Postpone in individuals with a febrile illness or acute infection</p>
<p><b>11. Presentation</b></p>	<p><b>11.1</b> Multi-dose vials (MDVs) of H1N1 influenza vaccine, either:</p> <ul style="list-style-type: none"> <li>▪ 5mL presentation (from which a maximum of 10 doses can be drawn).</li> <li>▪ 10mL presentation (from which a maximum of 18 doses can be drawn).</li> </ul> <p>The MDVs contain a small amount of thiomersal to maintain sterility of the vaccine. Refer to PI for more information.</p> <p>All Immunisation providers must refer to the “<b>Guidelines for the administration of pandemic (H1N1) influenza vaccine from multi-dose vials (MDV)</b>” prepared by the ATAGI and must ensure strict infection control procedures are followed.</p> <p><b>11.2</b> Pre-filled syringes of H1N1 influenza vaccine are available for use in children from 6 months to &lt; 3 years of age.</p> <ul style="list-style-type: none"> <li>• Thiomersal free</li> <li>• 0.25mL presentation</li> <li>• Administration needle attached to syringe</li> </ul>
<p><b>12. Storage</b></p>	<p><b>12.1</b> Store pre-filled syringes and unopened MDV between +2°C and +8°C at all times</p> <p><b>12.2</b> Store any prepared syringes from MDV and opened MDV vaccine between +2°C and +8°C in a suitably sized, clean container which is protected from light and labelled clearly with the <b>date and time</b> doses were drawn, the <b>name of the person</b> who prepared the doses, <b>vaccine name, vial batch number</b> and <b>expiry time of drawn doses</b>, until ready to be administered.</p> <p><b>12.3</b> Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred.</p> <p><b>12.4</b> Refrigerated syringes containing vaccine drawn from a MDV should be discarded at the end of the immunisation session <u>or</u> up to a <b>maximum interval of 4 hours</b> after the vaccines have been drawn up, whichever is earlier.</p> <p><b>12.5</b> Dispose of the multi-dose vial within <b>24 hours</b> of opening. This is regardless of the number of doses remaining in the opened vial.</p> <p><b>12.6</b> Panvax Junior<sup>®</sup> must be stored between 2°C and 8°C and stored in the original packaging until use to protect from light. Can be used till date of expiry.</p> <p><b>12.7</b> DO NOT FREEZE</p>

<p><b>13. Procedure</b></p>	<p><b>13.1 Pre-immunisation</b></p> <p>13.1.1 Obtain a detailed immunisation history.</p> <p>13.1.2 Refer to the relevant sections in the <i>Immunisation Handbook 9<sup>th</sup> Edition 2008</i><sup>1</sup>, for guidelines for pre-vaccination assessment including the <b>Pre-vaccination Checklist</b>.</p> <p>13.1.3 Refer to the H1N1 2009 Influenza Vaccination Program consent form and accompanying fact sheet as prepared by the Australian Government.</p> <p>13.1.4 Ensure valid consent is obtained.</p> <p><b>13.2 Preparing the Panvax® vaccine for administration</b></p> <p>Refer to the “<b>Guidelines for the administration of pandemic (H1N1) influenza vaccine from multi-dose vials (MDV)</b>” and the MDV checklist</p> <p>13.2.1 If drawing up several doses for immediate use during an immunisation session have a suitably sized, clean container which is protected from light and labelled clearly with:</p> <ul style="list-style-type: none"> <li>▪ the date and time doses were drawn;</li> <li>▪ the name of the person who prepared the doses;</li> <li>▪ vaccine name;</li> <li>▪ vial batch number; and</li> <li>▪ expiry time of drawn doses</li> </ul> <p><i>Discard the drawing up needle immediately into the sharps disposal container when finished. <b><u>Never leave a drawing up needle inserted into the multi-dose vial if you have finished drawing up as it leaves the vial vulnerable to contamination.</u></b></i></p> <p>13.2.2 Panvax Junior®</p> <ul style="list-style-type: none"> <li>• Remove from packaging</li> <li>• Inspect syringe to ensure intact</li> </ul> <p><b>13.3 Administering the vaccine</b></p> <p>13.3.1 Shake the pre-filled syringe or the MDV thoroughly, immediately before use. The vaccine should appear as a clear to slightly opaque liquid with some sediment that resuspends upon shaking.</p> <p>13.3.2 Check batch number and expiry date</p> <p>13.3.3 If using MDV, draw up the required number of vaccines following the recommendations in the “<b>Guidelines for the administration of pandemic (H1N1) influenza vaccine from multi-dose vials (MDV)</b>”.</p> <p>13.3.4 The vaccine should be administered by intramuscular or deep subcutaneous injection.</p> <p><b>13.4 Site considerations</b></p> <p>13.4.1 For infants 6 to &lt;12 months of age Administer into the vastus lateralis muscle of the antero lateral thigh</p> <p>13.4.2 For Adults, adolescents and children 12 months of age and older administer into the deltoid muscle</p> <p><b>13.5 Disposal</b></p> <p>Dispose of the used syringe and injection needle into an approved sharps container immediately after vaccine administration.</p>
<p><b>14. Side Effects</b></p>	<p><b>14.1 Common (within 7 days)</b></p> <p>Local – injection-site tenderness, pain and redness</p> <p>Systemic – headache, myalgia, malaise, fever, chills, nausea</p> <p>In children less than 5 years of age, these side effects may be more</p>

	<p>pronounced</p> <p><b>14.2 Very rare</b></p> <p>Anaphylaxis</p> <p><b>Post-marketing surveillance:</b></p> <p>There are currently no post-marketing data for Panvax<sup>®</sup> or Panvax Junior<sup>®</sup> H1N1 vaccine. It is anticipated that the adverse events after vaccination will be similar to those spontaneously reported during post-approval use of CSL's seasonal influenza vaccine, Fluvax<sup>®</sup> vaccine.</p>
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<p><b>15. Documentation</b></p>	<p><b>15.1 Record in the vaccine recipient's personal health record or other immunisation record card/book and in your clinical record/data file:</b></p> <p>15.1.1 valid consent obtained</p> <p>15.1.2 vaccine administered, route and site of administration;  <b><i>Each box of vaccines will contain stickers detailing batch number and expiry date. These stickers can be affixed to consent forms and in paper patient records.</i></b></p> <p>15.1.3 date of administration</p> <p>15.1.4 name and organisation of the person administering the vaccine</p> <p><b>15.2</b> Ensure Indigenous identification is documented on the consent form or in the clinic records</p>
<p><b>16. Monitoring requirements</b></p>	<p><b>16.1 Observation post-vaccination</b></p> <p>16.1.1 Vaccine recipients should remain in the vicinity for a minimum of 15 minutes for observation for potential life-threatening adverse events.</p> <p>Adults should be warned of the risk of driving or operating machinery for at least 30 minutes after vaccination.</p> <p><b>16.2 Post-vaccination advice</b></p> <p>Provide verbal and written information on common side effects and where to report any side effects</p>
<p><b>17. Management of Adverse Events Following Immunisation (AEFI)</b></p>	<p><b>17.1</b> Refer to Handbook<sup>1</sup> for the management of immediate AEFI (such as anaphylaxis) or vasovagal episode (faint)</p> <p><b>17.2</b> Report all AEFI of Panvax or Panvax Junior</p> <p>17.2.1 AEFI reporting form can be obtained at <a href="http://www.health.sa.gov.au/pehs/">www.health.sa.gov.au/pehs/</a></p> <p>17.2.2 Reports can be submitted to the Immunisation Section by:  phone: 8226 7177  Fax: 8226 7197; or  Post: PO Box 6, Rundle Mall, Adelaide, SA 5000</p>

# H1N1 vaccine for children 6 months to less than 10 years of age

## 6mths to less than 3 years

- Panvax Junior is available in single dose (7.5 micrograms in 0.25 mL) pre-filled syringes and is **approved for use only in children 6 months to less than 3 years**.
- Shake the pre-filled syringe vigorously to re-suspend any sediment before injection. The H1N1 Panvax vaccine is to be administered intramuscularly.
- Orders for Panvax Junior can be placed on the updated order form available on [www.flu.sa.gov.au](http://www.flu.sa.gov.au)

## 3 years to less than 10 years

- H1N1 Influenza 09 available in multi dose vials and currently in use for all those 10 years and over **is now approved for use in children from 3 yrs of age**.

## Co-administration with other childhood vaccines

- Panvax Junior and Panvax vaccine can be administered at the same time as other childhood vaccines but at a different site, and in separate syringes.
- Providers are encouraged to offer the H1N1 vaccine when parents present for routine immunisation visits.

The table below indicates the vaccine type and number of doses required for the relevant age groups.

Vaccine	Age	Presentation and dose	Recommended number of doses	Interval between doses
Panvax Junior®	6 months to < 3 years	Pre-filled syringe 7.5µg in 0.25 mL	2	4 weeks
Panvax® Multi dose vial	3 years to < 10 years	Multi-dose vial 15µg in 0.5 mL	2	4 weeks
	10 years and over	Multi-dose vial 15µg in 0.5 mL	1	

## Common reactions to Panvax in children

Vaccines, like any medication or natural therapy, can have side effects. Side effects from Panvax Junior and Panvax are similar to those from seasonal influenza vaccine. They are usually short lasting and may include:

- a. Pain, redness and swelling at the injection site
- b. Influenza-like symptoms including: fever, chills, headache, malaise and myalgia

It should be noted that in children less than 5 years of age, these side effects may be more pronounced.

## Notification to Australian Childhood Immunisation Register (ACIR)

- Providers are encouraged to notify the ACIR of Panvax Junior or Panvax vaccine doses administered to children less than 7 years of age.
- The Standing Drug Order (SDO) for H1N1 vaccine has been updated to include Panvax Junior and is available at [www.flu.sa.gov.au](http://www.flu.sa.gov.au)
- The Panvax Product Information (PI) has been updated and is available on the CSL website

## Administering seasonal influenza in children who have received 2 doses of Panvax

The Australian Technical Advisory Group on Immunisation (ATAGI) has issued advice that states "there are no specific restrictions on the time interval between receiving Panvax and seasonal influenza vaccine." Providers are encouraged to offer everyone from 6 months of age H1N1 vaccine. Those who will require seasonal influenza vaccine will benefit from a boosting effect of H1N1.

# Presentation and dosage guide

Quick reference guide – December 2009

Vaccine	Age	Presentation and dose	Recommended number of doses	Interval between doses
<b>Panvax Junior®</b> Pre filled syringe	6 months to < 3 years	Pre-filled syringe 7.5µg in 0.25mL	2	4 weeks
<b>Panvax®</b> Multi-dose vial	3 years to < 10 years	Multi-dose vial 15µg in 0.5mL	2	4 weeks
	10 years and over	Multi-dose vial 15µg in 0.5mL	1	NA

## Notification to Australian Childhood Immunisation Register (ACIR)

- Providers are encouraged to notify the ACIR of Panvax Junior® or Panvax® vaccine doses administered to children less than 7 years of age
- The Standing Drug Order (SDO) for H1N1 vaccine has been updated to include Panvax Junior® and is available at [www.flu.sa.gov.au](http://www.flu.sa.gov.au)
- The Panvax® Product Information (PI) has been updated and is available on the CSL website [www.csl.com.au](http://www.csl.com.au)

## For more information

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11 Hindmarsh Square  
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