Victoria Government Gazette

No. S 426 Thursday 26 November 2009
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Drugs, Poisons and Controlled Substances Act 1981
Section 22D

PUBLIC HEALTH EMERGENCY ORDER

I, Fran Thorn, Secretary to the Department of Health, make this public health emergency order in the belief that it is necessary to do so in order to prevent a serious risk to public health by decreasing the risk of further human infection with pandemic (H1N1) 2009 influenza (human swine influenza) in Victoria.

By this Order I authorise all nurses registered in Division 1 of the Register kept by the Nurses Board of Victoria under the **Health Professions Registration Act 2005**, who are employed by a public hospital, denominational hospital, privately operated hospital or public health service within the meaning of the **Health Services Act 1988**, to obtain and possess and use, the Schedule 4 poison Panvax® H1N1 vaccine.

Supply of the nominated drug is to be in accordance with the attached Schedule.

This order comes into force on 30 November 2009 and shall continue in force until 22 May 2010.

FRAN THORN
Secretary to the Department of Health

DETAILS OF DOSAGE AND ADMINISTRATION OF PANVAX®H1N1

Comprehensive information for the administration of the vaccine is available from the Panvax®H1N1 vaccine Guidelines for administration November 2009 located on the humanswineflu vic.gov.au website.

Indication	Any person ten years of age or older without contraindications to the vaccine (see below) who wishes to be vaccinated. Particular emphasis will be given to vaccinating the following priority groups: • Pregnant women in any trimester of pregnancy • Adults and children ten years of age and over with underlying chronic medical conditions • Individuals with moderate to severe obesity (BMI>35) • Health care workers • Community care workers • Children aged ten years and over attending special schools • Indigenous people aged ten years and over • Parents and guardians of babies aged 0 to 6 months.
Limit to the provision of vaccination	Division 1 Registered nurses may only administer the vaccine in the course of their employment

Presentation	The Panvax® H1N1 vaccine is presented in multi-dose vials (MDV). It is a monovalent vaccine which contains the A/Calfornia/7/2009 (H1N1) v-like virus. Each vial contains a small amount of the preservative Thiomersal. Thiomersal retards bacteria and fungal growth within the vial. The vaccine vial has a latex-free rubber stopper. Box 50, 10 ml vials 18 doses per vial (= 900 doses) Box 10, 10 ml vials 18 doses per vial (= 180 doses) Box 10, 5 ml vials 10 doses per vial (= 100 doses) Pre-filled syringes (at a later time) 0.25 ml = 7.5 mcg (paediatric use only)
Use of Multi-dose vials (MDV)	The use of a MDV is not common in Australia. To prevent the potential transmission of infectious disease through vial contamination, medical errors, reduce wastage and ensure the delivery of a potent vaccine to the client, it is essential that all immunising staff are educated on the use of MDV. The Australian Technical Advisory Group on Immunisation (ATAGI) has prepared comprehensive guidelines on the safe use of MDV. It is essential that each immunisation provider reviews and understands the MDV guidelines prior to immunising. For a copy of the ATAGI guidelines refer to **(Appendix E)** or go to the Australian Government Department of Health and Ageing, Health Emergency website at http://www.healthemergency.gov.au/internet/healthemergency/publishing.nsf/Content/national-vaccination-program#mdv The MDV guideline includes the following: 1. Equipment required 2. Procedure A. When a single dose is required (e.g. for opportunistic vaccination) B. Non-dedicated immunisation settings (When a small number of doses, e.g. between 2 and 9 doses, are required) C. Dedicated immunisation settings (where many doses of vaccine are being administered during a session)
Storage requirements	A person authorised by this Order must keep all supplies of Panvax® H1N1 in their possession in a lockable storage facility; and take all reasonable steps to ensure that the storage facility remains locked and secured to prevent access by an unauthorised person at all times, except when it is necessary to open it to carry out an essential operation in connection with use or supply in accordance with this Order. The Panvax® H1N1 vaccine must be stored in keeping with the cold chain guidelines documented in The Australian Immunisation Handbook and the National Vaccine Storage Guidelines Strive for 5: ● Panvax® H1N1 vaccine must be protected from freezing and from light ● Should the vial be removed from its original packaging ensure that it is placed in a light proof container

	• Maintain refrigerator temperature between +2°C to +8°C • Check and record the current minimum/maximum temperatures at least daily or immediately before vaccines are used • If a cold chain breach appears to have occurred contact the Immunisation Program on 1300 882 008 before using or discarding the effected vaccines • Keep refrigerator door openings to a minimum • Ensure one person is responsible for adjusting refrigerator controls and that all staff are appropriately trained to ensure continuous monitoring • Ensure one staff member is designated the role of administrator of vaccines and vaccine storage. The National Vaccine Storage Guidelines: Strive for 5: http://www.health.gov.au/internet/immunise/publishing.nsf/content/provider-store
Record keeping requirements	A person authorised by this Order is recommended that the Australian Government developed consent form be used. If a written consent form is not used in a clinic, valid verbal consent must be obtained and documented in the client's medical history along with the following information: • Name of vaccine (if not using provided consent sheet) • The batch sticker or number of the vaccine • The date of vaccine administration • The signature of the vaccinator • Provider name and telephone contact. A record of the administration of the Panvax® H1N1 to children aged under 7 years should be lodged with the ACIR. A consent form can be scanned into the patient's record and then discarded appropriately. The person providing the vaccination must also provide the vaccine recipient with the tear-off slip on the bottom of the consent form or something similar which includes the above information. Where a patient has received the vaccine as an inpatient in a hospital it is recommended that the information is also documented on the patient's discharge summary along with the above listed information given to the patient. Completed consent forms must be stored in keeping with the Privacy Policy of individual immunisation service providers. The records must be maintained, in English, in readily retrievable form, and kept for not less than 3 years from the date of the transaction. The records must be produced on demand to the Secretary to the Department of Health or her delegate.

Contraindications	Absolute contraindications to the Panvax® H1N1 vaccination are: ● Anaphylaxis following a previous dose of any influenza vaccine ● Anaphylaxis following any vaccine component, including the antibiotics neomycin or polymyxin B sulphate ● Infant under six months of age ● Severe allergy to eggs.
Precautions	Panvax® H1N1 vaccine and vials are both latex-free. However, the plunger of the 1 mL syringe provided in the VacPacs contains latex. Providers should specifically ask about a history of allergic reactions to latex or latex-containing products before Panvax® H1N1 vaccine administration. A person with an anaphylactic allergy to latex can receive the Panvax® H1N1 vaccine taking careful precautions to avoid latex exposure as follows: ● Do not use the 1 mL syringe provided in the VacPacs – use a LATEX FREE syringe. ● Use a new multi-dose Panvax® H1N1 vial, to eliminate the possibility of latex contamination of the vaccine from other latex-containing syringes used to draw up previous doses. If there is any doubt about latex allergy, it is prudent to use LATEX FREE syringes. Concern has been raised whether recipients of Panvax® H1N1 vaccine might have a small increased risk of developing Guillain-Barré Syndrome (GBS), such as was observed with an H1N1 vaccine against 'swine flu' in 1976–1977 in the USA. ATAGI has made recommendations in accord with the 9th Edition of The Australian Immunisation Handbook, page 193. The ATAGI information on GBS is available online at www.healthemergency.gov.au
Drug interactions	No significant interactions known. Panvax® H1N1 vaccine can be administered concurrently with other vaccines, however, separate syringes and separate injection sites should be used for each vaccine. The immunological response to the Panvax® H1N1 vaccine may be diminished if the client is undergoing corticosteroid or immunosuppressant treatment.
Side effects	Some common known mild to moderate self limiting, adverse events reported following the administration of the Panvax® H1N1 vaccine are: ● localised reaction at the injection site; as many as one in ten people report some: – swelling – redness and/or – pain at the injection site ● fever ● tiredness ● headache ● muscle aches.

<table>
<tr><td></td><td>Onset of adverse events can be within a few hours of vaccination and may last for one to two days.
Vasovagal (fainting) episodes are relatively common after vaccination of adult and adolescents, but infants and children rarely faint. Immunisation providers must be able to distinguish between anaphylaxis, convulsions and fainting.
The most serious immediate AEFI is anaphylaxis which is very rare but can be fatal. Usually anaphylaxis has a rapid onset following immunisation and the 15-minute waiting period post-vaccination should be observed. Immunisation providers should be familiar with the signs of anaphylaxis and respond appropriately.</td></tr>
<tr><td>Administration</td><td><table>
<tr><th>Age or size of child/adult</th><th>Needle type</th><th>Angle of needle insertion</th></tr>
<tr><td>Child or adult for IM vaccines</td><td>23 or 25 gauge*, 25 mm in length†</td><td>90° to skin plane</td></tr>
<tr><td>Very large or obese patient</td><td>23 gauge, 38 mm in length</td><td>90° to skin plane</td></tr>
</table>The deltoid muscle is the recommended site for IM vaccination in adolescents and adults. Children aged under 12 months the site for the IM injection is the vastus lateralis muscle in the anterolateral thigh.</td></tr>
<tr><td>Special information for children from 6 months to< 10 years of age:</td><td>The vaccine is not yet licensed for use in infants and children aged six months to less than 10 years.
Infants less than 6 months of age are not recommended to receive Panvax® H1N1 vaccine.</td></tr>
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*If using a 25 gauge needle, ensure vaccine is injected slowly over a count of five seconds to avoid injection pain and muscle trauma.

†The use of short needles for administering IM vaccines may lead to inadvertent subcutaneous (SC) injection and increase the risk of significant local adverse events.

(Reference: The Australian Immunisation Handbook 9th Edition 2008 page 45).

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