

MH 34:85

26 November 2009

All Medical Clinics

**MOH CIRCULAR 108/2009  
INFLUENZA A/H1N1 (2009) VACCINES UPDATES**

Pandemrix®, GSK

1. The H1N1 vaccine from Glaxo-SmithKline (GSK) is now available. For your information, GSK's vaccine (**Pandemrix®**) is an adjuvanted vaccine which will require reconstitution of the Antigen and Adjuvant. The antigen and adjuvant are contained in separate vials. Clinics will be offered the flexibility to order either, the **Panvax®, CSL** or **Pandemrix®, GSK** vaccines or **both**. Please refer to **Annex A** for a comparison of the vaccines.

2. The current approval of **Pandemrix®, GSK** remains for persons aged 18 years old and above only. MOH's Expert Committee on Immunisation (ECI) recommends that **one dose of 0.5ml (3.75 mcg)** is sufficient. Please note that this single dose recommendation was made after a recent review of data and differs from the two doses regime previously recommended, which was already printed in the current vaccine product insert. The prescribing information of the vaccines will be updated from time to time as new data emerges, hence prescribers should refer to the latest package inserts published on Health Sciences Authority (HSA) website, at <http://www.hsa.gov.sg>. The specific information can be located at the webpage titled "Influenza A – H1N1".

Use in Children

3. **Panvax®, CSL** has been approved by HSA for children aged **10 years and above** for the time being, pending further reviews of safety data in the younger age groups. The recommendation for children 10 years and above is a **single dose of 0.5 mL (15 mcg)**, which is similar to the current adult dose recommendation.

Use in Pregnancy

4. There are no studies conducted in pregnant women using H1N1 vaccines. However, studies in experimental animals using non-adjuvanted or adjuvanted vaccines found no evidence of direct or indirect harmful effects on fertility, pregnancy, development of the embryo or fetus. Based on these data and the substantially elevated risk for a severe outcome in pregnant women infected with the pandemic virus, the ECI has recommended that vaccination may be considered for use in pregnant women during the second and third trimester.

5. Physicians should however, exercise their professional judgement in assessing the risks versus benefits of the vaccine for the individual pregnant patient. Due to the longer track record of safety of the non-adjuvanted vaccines for pregnancy in general, it is recommended that non-adjuvanted vaccines, if available (e.g. **Panvax**®, **CSL**) should be used instead of adjuvanted vaccines for this group of patients. If in doubt, the patient may also be referred to an obstetrician for assessment on recommendation for the H1N1 vaccination.

#### Co-administration of H1N1 vaccine and other vaccines

6. The H1N1 vaccine available in Singapore is an inactivated vaccine. Inactivated vaccines in general may be administered simultaneously or at any interval apart from other vaccines. However, while data available to date has shown the vaccine to be safe, clinical trials to establish its safety and efficacy profile are still ongoing. Thus, it is recommended that H1N1 vaccine be administered at an interval of at **least 1 week apart** from any other vaccine, so that the occurrence of any adverse reaction may be attributed to the correct causative agent.

#### Order and Payment

7. All registered clinics may wish to place an order of the H1N1 vaccines via the MOH-appointed distributor, Zuellig Pharma. Orders can be made using the revised form attached as **Annex B** and faxed to **1800-546-9088**. Billing and payment would be conducted directly between the clinics and Zuellig Pharma.

#### Terms and Conditions

8. The terms and conditions including requirements for notification and safety monitoring stated in MOH Circular 105/2009 (dated 29 October 2009) remains valid. Please also refer to **Annex C** for instructions on mixing and reconstitution of the antigen and adjuvant vials for **Pandemrix**®, **GSK**.

9. For further clarification of this circular, please email us at [moh\\_info@moh.gov.sg](mailto:moh_info@moh.gov.sg)



PROF K SATKU  
DIRECTOR OF MEDICAL SERVICES

cc CEOs, Singhealth and NHG Polyclinics  
President, Singapore Medical Association  
President, College of Family Physicians, Singapore  
CEO, Health Promotion Board  
CEO, Health Sciences Authority

Vaccine	Panvax ®, CSL	Pandemrix ®, GSK
Composition	Non-adjuvanted	Adjuvanted
Dosing requirement	<u>Adults and children 10 years and above:</u> Single dose of <b>0.5 mL (15 mcg)</b>	<u>Adults 18 years of age and above:</u> Single dose of <b>0.5 mL (3.75 mcg)</b>
Constitution	Single multi-dose vial of 5 mLs. Each vial contains sufficient volume for 10 doses. Each dose will equal to 0.5 mL.	Each reconstituted vial of Antigen and Adjuvant contains sufficient volume for 10 doses. Each dose will equal to 0.5 mL.
	Single dose of 0.5 mL in a prefilled syringe	No single prefilled syringe available
Packaging	10 vials per box	1 vial of Antigen and 1 vial of Adjuvant per box
	1 prefilled syringe per box	Not Applicable
Administration	Each vial of 10 doses must be used within 24 hours. Any remaining unused vaccine must be discarded after 24hrs.	Each vial of antigen and adjuvant must be mixed and reconstituted before administration. Each reconstituted vial of 10 doses must be used within 24 hours. Any remaining unused vaccine must be discarded after 24hrs.
Side-effects	Similar to seasonal flu vaccines	
Cost	\$17.00 (inclusive of GST) <u>per dose of 0.5 mL</u>	
Storage conditions	H1N1 vaccines should be stored and protected from light, at <b>+2°C to +8°C. DO NOT FREEZE.</b>	
Expiry date	Varies with different batches	



## ZUELLIG PHARMA

15 Changi North Way, #01-01, Singapore 498770

### **PANDEMIC VACCINE ORDER FORM (REVISED)**

Name of Organisation/Clinic: \_\_\_\_\_ Customer Code: \_\_\_\_\_

Please indicate if your clinic is a Pandemic Preparedness Clinic (PPC): Yes / No (please circle)

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

Email: \_\_\_\_\_ Contact Person: \_\_\_\_\_

#### **For the supply of:**

CODE	DESCRIPTION	PRICE per box (before GST)	MINIMUM ORDER QUANTITY	QUANTITY (number of boxes)
998CSL001	<b>PANVAX®, CSL</b> Multi-dose vial (10 doses/vial), 10 vials per box	\$1,588.00	1 box	
998CSL002	<b>PANVAX®, CSL</b> Single-dose prefilled syringe, 1 syringe per box	\$15.88	Multiples of 10 boxes	
998GSK001	<b>PANDEMRIX®, GSK</b> Multi-dose vial (10 doses/vial), 1 vial of antigen & 1 vial of adjuvant per box	\$158.80	1 box	

#### **Approved by:**

Signature: \_\_\_\_\_ Name: \_\_\_\_\_

Date: \_\_\_\_\_ MCR No: \_\_\_\_\_

- Please **FAX** completed form to **Customer Service Fax: 1800-546-9088**
  - **All Goods are non-returnable**
  - Allocation of vaccines will be on a first-come-first serve basis
  - The following surcharge is applicable for delivery of allocated vaccines:
    - Surcharge for urgent delivery (4 hours) @\$30/order
    - Surcharge for Scheduled delivery outside office hour @\$30/order
    - Surcharge for urgent request for stock outside office hour @\$200/order (hotline: 6548 1758/ 1759)
- (NB: Office hour refers to 8.30am to 5.30pm Monday to Friday, exclude Saturdays, Sundays & Public Holidays)

---

*For Zuellig Pharma Use*

Dear Customer,  
Thank you for your order. Your order has been processed and we will inform you of the expected delivery date.

Your Order Number is: \_\_\_\_\_ Date: \_\_\_\_\_

**Pictorial Reconstitution Guide for PANDEMRIX®, GSK****Instructions for Use/Handling****The H1N1 Vaccine consists of two containers:**

- Big Vial : one multidose vial containing the antigen (suspension which is colourless light opalescent liquid)
- Small Vial : one multidose vial containing the adjuvant (emulsion which is a whitish homogenous liquid).

**Instructions for mixing and administration of the vaccine:**

- Step 1** Before mixing the two components, the adjuvant (emulsion) and antigen (suspension) should be allowed to reach room temperature (25 °C), shaken and inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.
- Step 2** The vaccine is mixed by withdrawing the contents of the vial containing the Adjuvant emulsion (Small Vial) by means of a syringe (5ml) and needle (20G) and by adding it to the vial containing the Antigen suspension (Big Vial).
- Step 3** After the addition of the adjuvant to the antigen, the mixture should be well shaken. The mixed vaccine is a whitish emulsion. In the event of other variation being observed, discard the vaccine.
- Step 4** Label on the carton the **DATE** and **TIME** it was reconstituted for record as the mixed vaccine can only be used within 24 hours.
- Step 5** The volume of H1N1 Vaccine (5 ml) after mixing corresponds to 10 doses of vaccine.
- Step 6** The vial should be shaken prior to each administration.
- Step 7** Each vaccine dose of 0.5 ml is withdrawn into a 1 ml syringe with a 20G needle.

- Step 8** Replace the needle used for withdrawal of vaccine by a needle (23G or 25G) suitable for intramuscular injection.
- Step 9** The reconstituted vial can be used immediately or stored for future vaccine administration but can be used within 24 hours only (do not store above 25°C). Any remaining unused vaccine is to be disposed in accordance with local requirements after that.

**Details of Needles and Syringes**

Specification of Syringe	Specifications of Needles	Use
5ml	20G	Reconstitution
1ml	20G	Withdrawal of reconstituted vaccine
1ml	23G or 25G	Administration of Vaccination

Per Multidose vial of the vaccine

**For withdrawal of Adjuvant into the Antigen vial:-**

- 1 syringe (5ml) + needle 20G (1" or 1 ½") to transfer adjuvant into antigen vial.
- The adjuvant has an overfill so draw out as much of adjuvant as possible. There will still remain some dead volume into the adjuvant vial as it may not be possible to draw 100% of the contents.

**For Vaccination of patients:-**

- 10 syringes (1 ml) + 1 needle 20G (1" or 1 ½") to withdraw 0.5ml dose will be needed
- Needle can be left in rubber seal only if several injections are made in succession (it is best practice to change the withdrawing needle with each administered dose. However during mass vaccinations it is common practice to only use one withdrawing needle when vaccinations are given in succession).

• If the needle is removed it can not be reused and a new needle will be required for subsequent withdrawal

- 10 needles of 23G or 25G (1") for vaccine injection in patients will be needed

Note: There maybe some wastage due to dead space in needles, syringes etc.

**Precautions with Multi-dose vials:**

- The primary risk with use of multi-dose vials is infection due to user error.
- Multi dose vials can be contaminated when for e.g.:
  - An un-sterile needle is inserted into the vial
  - A needle is left in the vial for multiple redraws
  - A contaminated syringe is used
- Therefore careful adherence to appropriate infection control protocols are necessary.

**Storage Guidelines:**

**Before Reconstitution**

- Store in a refrigerator +2°C to +8°C
- Store in the original package in order to protect from light.
- Do not freeze.

**After Reconstitution**

- After mixing, the vaccine should be used within 24 hours (do not store above 25°C, preferably between 2°C to 8°C).
- Store reconstituted vial in the original package to protect from light.