

**Ministry of Health
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**Ministère de la Santé
et des Soins de longue durée**

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December 10, 2009

To: ONTARIO PHARMACISTS' ASSOCIATION

**RE: Immunization Clinics in the Pharmacy Setting-Seasonal and Pandemic Influenza H1N1-2009
Immunization Program**

Dear Colleague:

Thank you for participating in this year's Universal Influenza Immunization Program (UIIP) in the province of Ontario. Ontario's UIIP has been expanded to invite pharmacies to offer H1N1 and/or seasonal influenza vaccine clinics to the general public. Vaccine delivery agencies approved by the ministry through a prequalification agreement to deliver H1N1 and/or seasonal vaccine, received written confirmation on October 6, 2009, regarding the H1N1 and seasonal Universal Immunization Program (UIIP).

The ministry would like to ensure that pharmacists who are offering H1N1 and/or seasonal influenza clinics are well informed about the program. The information and documents that apply to vaccine delivery agencies provided in the "*H1N1-2009 Implementation Package*" section of this letter can be accessed at the following link: <http://mohltc.ca/Page55.aspx>, using the login information for pharmacies. If pharmacists are planning to hold immunization clinics for both H1N1 and seasonal vaccine they need to ensure that the vaccine delivery agency is approved by the ministry.

Product Information Leaflets for H1N1 Vaccine

Information about the H1N1 vaccines is posted on the Health Canada website at the following link: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/prodinfo-vaccin-eng.php>. Please review this website frequently for regular H1N1-2009 vaccine updates. The ministry will also notify you of any updates as they become available.

The product information leaflets have also been posted online under "pharmacy" and can be accessed with your username and password at the following link: <http://www.health.gov.on.ca/en/ccom/flu/h1n1/pro/>. These documents will be updated on a regular basis as more information on the vaccine is received and reviewed by the Biologics and Genetic Therapies Directorate (BGTD).

Phases of Influenza Immunization Programs

This year is a different influenza year in Ontario, requiring 3-phases to immunize against the influenza virus. At the present time phases 2 and 3 are operating simultaneously.

H1N1-2009 Implementation Package

The H1N1-2009 Implementation package for pharmacy is posted on the ministry's general influenza website at: <http://www.health.gov.on.ca/en/ccom/flu/h1n1/pro/>, this link was previously www.gettheflushot.ca. The username and password needed to access the H1N1 and/or Seasonal Influenza Immunization Packages for the pharmacies is below:

INFORMATION PACKAGE FOR H1N1/UIIP	USERNAME	PASSWORD
pharmacy	pharm	Vaccine2

The H1N1-2009 Implementation package contains the following documents:

- H1N1-2009 Influenza Virus Qs & As
- H1N1-2009 Influenza Fact Sheet
- Informed Consent
- Recommended Recipient Groups for the Pandemic H1N1-2009 Vaccine
- Groupes de receveurs recommandés pour le vaccin contre la grippe pandémique H1N1 2009
- H1N1 Vaccine Order Form – “M” postal code (Toronto)
- H1N1 Vaccine Order Form – outside of “M” postal code (excluding Toronto)
- Adverse Events Following Immunization Reporting Form and User Guide
- Pharmacovigilance and Vaccine Safety
- Regulation of the H1N1 Pandemic Influenza Vaccine
- Vaccine Utilization Report Form for Pharmacies
- Product Information Leaflet Arepanrix™ H1N1 AS03-Adjuvanted H1N1 Pandemic Influenza Vaccine
- Arepanrix™ Reconstitution Recommendations
- Addendum to the October 21, 2009 – Guidance Document on the Use of Pandemic Influenza A (H1N1) 2009 Inactivated Monovalent Vaccine
- Panvax® H1N1 Vaccine Product Information - Australia
- Panvax® H1N1 Vaccine – H1N1 Pandemic influenza vaccine (split virion - inactivated) (English and French versions)
- Unadjuvanted H1N1-2009 Influenza Vaccine Fact Sheet for Pregnant Women
- H1N1-2009 Influenza Qs & As – Focus on Panvax®

Supplies Available for H1N1-2009 Vaccine Delivery

Organizations willing to administer H1N1 vaccine may have the opportunity to order supplies from the ministry to support them in the H1N1 vaccine administration process only.

Pharmacies who retain a vaccine delivery agency to administer H1N1 Vaccine

Pharmacies that would like to administer both H1N1 and Seasonal influenza vaccine at their clinics must ensure that the organization retained to administer the aforementioned influenza clinics have prequalified with the ministry to provide both H1N1 and Seasonal influenza vaccine. Pharmacies should be aware that not all organizations that have prequalified to administer seasonal influenza vaccine have also prequalified to administer H1N1 Vaccine. General information about vaccine delivery agencies that can be retained to administer H1N1 and/or Seasonal vaccine is found at the following link:

<http://www.health.gov.on.ca/en/ccom/flu/h1n1/wpl/>

Submission of Vaccine Utilization Invoices to the local health unit

H1N1 and/or seasonal influenza vaccine immunizations that are provided in the pharmacy clinic setting are eligible for reimbursement of \$5.00/dose by the ministry. Organizations that administer influenza vaccine in

the pharmacy setting are requested to complete the vaccine utilization report available on the "pharmacy" link available at: <http://www.health.gov.on.ca/en/ccom/flu/h1n1/pro/>, and submit this information to the local health unit no later than 10 days after the immunization clinic. Note that the Ontario Drug Benefit Number (ODB Number) must be present on the Pharmacy Invoice in order to be eligible for reimbursement of \$5.00/dose by the ministry.

Each Vaccine Utilization Report Form for Pharmacies should be submitted to the local health unit no later than 10 days after the H1N1 immunization clinic. The health unit will provide all vaccine utilization invoices to the ministry. Please note that the ministry is only requesting aggregate information on priority group coverage in Part E of the Vaccine Utilization Report Form for Pharmacies in respect of seasonal influenza immunizations, and not for H1N1 immunizations.

Also, pharmacies should note that their collection, use and disclosure of personal health information (PHI), including PHI collected by pharmacies at influenza immunization clinics, is subject to the *Personal Health Information Protection Act, 2004* ("PHIPA"). Accordingly, pharmacies should ensure that they are complying with PHIPA when collecting PHI during immunization clinics, including any relevant consent and notice requirements in PHIPA. These requirements may vary depending on the PHI being collected and the purpose that it is being collected for.

Pharmacies should consult with their legal counsel and privacy experts as necessary. However, the best practice is to always provide individuals with, at a minimum, notice explaining what PHI the pharmacy is collecting, why and how it is being collected and in what form it may be subsequently used and disclosed. Furthermore, since consent to the collection, use and disclosure of PHI under PHIPA must be knowledgeable, it must be reasonable in the circumstances to believe that individuals know that they may give or withhold their consent, as well as the purpose for which their PHI may be collected, used and disclosed. Accordingly, as a best practice, individuals' rights to give and withhold consent should also be set out in pharmacies' notices describing the collection, use and disclosure of PHI.

It is also advisable to use separate documentation for consents to treatment (i.e. immunizations) and information-related notices or consents (such as statements posted in a clinic area or on a separate page of information), to avoid confusion among patients about consent to treatment and consent for information collection issues.

For clarity, the ministry uses the aggregate age, gender and priority group (for seasonal influenza immunizations) information that pharmacies and vaccine delivery agents report for the purposes of determining influenza vaccine uptake in the province; and for ongoing program analysis, evaluation and improvement.

Additional H1N1 Vaccine Information

Additional H1N1 information is available at: http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vaccine_vaccin-eng.php.

Pandemic Influenza H1N1-2009 Vaccine Supply	
Vaccine Strain	A/California/7/2009 (H1N1)-like virus
Vaccine Products	<p>Arepanrix™ (with adjuvant), produced by <i>GlaxoSmithKline (GSK)</i>. One multi-dose vial containing the antigen suspension and a second vial containing the adjuvant; an oil-in-water emulsion (AS03) (emulsion is a whitish homogenous liquid).</p> <p>Influenza A (H1N1) 2009 Monovalent Vaccine (without adjuvant), produced by <i>GSK</i>.</p> <p>Panvax® (without adjuvant), produced by <i>CSL Limited</i>.</p> <p>NOTE: These purified, detergent-split, inactivated, monovalent virus containing influenza vaccine products are propagated in eggs.</p>
Thimerosal-Free	Not available through the H1N1-2009 Immunization Program
Single Dose Format	Not available through the H1N1-2009 Immunization Program
Latex-Free	All three products are latex-free

Antibiotic-Use	Arepanrix™ and Influenza A (H1N1) 2009 Monovalent Vaccine are free of antibiotics Panvax® contains trace residual amounts of neomycin and/or polymyxin B sulfate
Formaldehyde Use	Arepanrix™ and Influenza A (H1N1) 2009 Monovalent Vaccine contain trace residual amounts of formaldehyde Panvax® is free of formaldehyde
Egg-proteins	All three products contain trace residual amounts of egg-proteins
Sodium deoxycholate	All three products contain trace residual amounts of sodium deoxycholate
Sucrose	All three products contain trace residual amounts of sucrose
Light Sensitivity	All three products are sensitive to light and must be contained in packaging that provides protection from light.

Should you or your staff have any questions regarding the H1N1-2009 Immunization Program, please contact the ministry via email at: UJIP.MOH@ontario.ca and either Rachel Brown (Nurse Consultant) or Nicole Kain (Nurse Consultant) will respond to your enquiry as promptly as possible. You may also contact your local health unit for information pertaining to a particular jurisdiction, a list of local public health units can be found at: http://www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html.

Thank you for your cooperation and efforts in implementing this program.

Sincerely,



Nina Arron
Director

c. VPD Managers, AMOH/MOH
R. Basur, Manager, OGPMS, Customer Service
Pharmacy Association