

April 9, 2010

RE: News Regarding Adjuvanted Pandemic H1N1 Vaccine – Arepanrix

The Biologics and Genetic Therapies Directorate (BGTD) - Health Canada, in consultation with GlaxoSmithKline, has advised provinces and territories that the antigen component of the adjuvanted H1N1 influenza vaccine (Arepanrix) prepared for use in the fall of 2009 declines in strength of the antigen prior to the 18 month expiry dates for which they were previously approved. Health Canada has advised that the expiry dates for unused vaccine antigen should be revised downward by 12 months.

What this means to physicians and pharmacists:

- Review any Arepanrix vaccines you have in your fridge.
- Subtract 12 months from the currently indicated expiry date on the antigen vial.
- For any lot of Arepanrix with an original expiry date for the antigen of March 31, 2011, change the expiry date to March 31, 2010 and place it on hold in your fridge in a separate box marked – “Do not use – Expired”. This should not be given to patients. Note that the antigen within each combination of antigen and adjuvant has a different unique lot number, separate from the adjuvant.
- Your local health unit in your health authority will let you know what to do with expired product.
- For any lots of Arepanrix with an original expiry date for the antigen of April 30, 2011, change that to April 30, 2010. This vaccine can be used for patients until the new expiry date, at which time it should be put on hold and not used.
- This is not an issue related to vaccine safety.
- There was no vaccine delivered to British Columbia with original expiry dates of the antigen prior to March 31, 2011, so anyone immunized before March 31, 2010 can be assured that the product they received met regulatory standards.
- Arepanrix with original expiry dates of March 31, 2011 was distributed throughout BC in October and early November, and little or none may be remaining in inventory.
- As the antigen content declines slowly, even if patients received a dose of Arepanrix in the first week of April from a lot with an original expiry date of March 31, 2011, it is likely to have had sufficient potency. Re-immunization of those patients is not recommended.
- If you need additional vaccine for your patients after April 30, 2010, there is both adjuvanted vaccine with May 2010 dating and unadjuvanted vaccine [Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)] which is unaffected by the expiry date change of the adjuvanted product, available in BC from your local health unit.

Background:

Working with GlaxoSmithKline, Health Canada has revised the provisional expiry date of the adjuvanted H1N1 vaccine (Arepanrix). Potency testing has determined that the expiry date for unused lots should be revised to 6 months from production instead of 18 months. It has been observed that the stability of the antigen, and thus the strength to induce an excellent immune response, declines with time.

There is no evidence that a shorter shelf-life has any impact on the immunity of those already immunized. There is no evidence that a person immunized with a product that would now be considered beyond the expiry date would experience any unusual effects.

There is almost no H1N1 influenza circulating in BC at this time, but some southern hemisphere jurisdictions are experiencing a second wave. It is not possible to say whether BC will experience a third wave in the coming months.

Your remaining inventory of Arepanrix with a newly adjusted expiry date of April 30, 2010 may continue to be used for those individuals wishing to be immunized against H1N1. Clients wishing to be immunized, or who are travelling to areas of the world where H1N1 is circulating, should not be turned away.

For more information please refer to the Health Canada Advisory at http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2010/2010_54-eng.php.