Influenza A (H1N1) 2009 Pandemic Vaccine
Arepanrix™ H1N1

1. What is Arepanrix™ H1N1?

Arepanrix™ H1N1 is a vaccine that was developed to protect against the Influenza A (H1N1) pandemic virus. Vaccines prevent illness by stimulating the production of antibodies (immune response) against the flu virus components. The vaccine contains an inactivated (non-live) version H1N1 virus strain that is recommended by the World Health Organization for the manufacture of vaccines during this influenza pandemic.

2. How is Arepanrix™ H1N1 administered?

The vaccine is to be administered by health professionals.

Arepanrix™ H1N1 is a two-component vaccine consisting of an antigen and an adjuvant. The antigen is the active ingredient in the vaccine that provides protection against the virus. The adjuvant is a substance that is added to the vaccine to boost the immune response. Prior to administration, the adjuvant is added to the antigen vial. After combining the two components, the vaccine is given by injection into the shoulder muscle.

3. How many doses are needed?

Preliminary data suggests that only one dose of Arepanrix™ H1N1 may be needed to produce an adequate immune response in adults aged 18-60 years. The need for a second dose is unknown at this time. Dosing recommendations will be updated as new information becomes available. Refer to the product leaflet for dose recommendations for various age groups.

4. What evidence was used to support the authorization of Arepanrix™ H1N1?

A prototype or "mock" vaccine was developed in the pre-pandemic period using another strain of influenza virus, the H5N1 strain. During this period Health Canada inspected the vaccine manufacturing facilities, validated the vaccine production process, and reviewed results from both animal and human studies with the mock vaccine. In addition, the safety and effectiveness of the adjuvant to be used with the vaccine was assessed by Health Canada. Once the H1N1 virus emerged as the pandemic virus, the manufacturer initiated vaccine production using the strain recommended by the WHO.

The following data was used to support approval of Arepanrix™ H1N1:

- Quality (chemistry and manufacturing) data on the vaccine manufacturing process to support the strain change from H5 to H1,

- Information from non-clinical (animal studies) and clinical studies in humans conducted with Arepanrix™ and Pandemrix™, a similar H1N1 pandemic vaccine manufactured by GSK in Germany, and
- Safety and other data from the review of the prototype H5N1 vaccine.

Data from clinical trials that became available globally during the authorization process using similar or related pandemic vaccines were also considered. Further clinical studies and surveillance will continue post-authorization.

5. What are the benefits and potential risks associated with Arepanrix™ H1N1?

Criteria have been established to assess the immunogenicity of vaccines. Clinical trial results indicate that Arepanrix meets all of these criteria, which means that the vaccine produces an adequate level of protection against the H1N1 pandemic virus.

As with all medicinal products, there may be side effects or adverse events associated with the use of the product. Some of the very common adverse events that have been observed in clinical trials with the pandemic vaccine include pain at the injection site, fatigue, headache, swollen glands in the neck, joint pain, and muscle ache. Refer to the product leaflet for additional information on adverse events.

Individuals should not be given the vaccine if they have a history of a severe allergic reaction to any of the ingredients that are in the vaccine. These ingredients include eggs or egg products, or chicken proteins. Refer to the product leaflet for a full list of vaccine ingredients. Individuals should not take the vaccine if they have previously experienced a life-threatening reaction to any other influenza vaccine.

6. How was Arepanrix™ H1N1 authorized?

Arepanrix™ H1N1 was approved because it was shown that the benefits of the vaccine outweigh any risks. The time frame between vaccine manufacturing and the need to use the vaccine in time to provide the public with protection against the virus is very short. As a result, it has not been possible for the manufacturer to collect the usual full information necessary for a Notice of Compliance to be issued under the *Food and Drug Regulations*. For this reason, an Interim Order was used to provide an alternate pathway to allow for the authorization for sale of the vaccine. Under the Interim Order, the manufacturer is required to continue submitting data on the safety and effectiveness of the vaccine. Health Canada and the Public Health Agency of Canada will review this information as it becomes available.

7. Does the company have to submit additional data on the vaccine?

Yes, the manufacturer will continue to submit data on the safety and effectiveness of the vaccine as it is rolled out. This data will include the results from ongoing clinical trials.

8. What measures are in place to monitor vaccine safety?

Various mechanisms are in place to monitor the safety and effectiveness of Arepanrix™ H1N1. Once authorized, all lots of the pandemic vaccine will be tested in Health Canada laboratories before they are released on the Canadian market.

The manufacturer is responsible for collecting information on the safety of the vaccine. This includes information on any adverse events that are reported following immunization. The Public Health Agency of Canada as well as other research organizations will also be actively monitoring the safety and effectiveness of the vaccine. The purpose of vaccine safety monitoring is timely identification of clinically significant adverse events following immunization that may be of public health concern

Health Canada and the Public Health Agency of Canada have been working in close collaboration with other national regulatory and public health authorities to respond to the pandemic virus. There is a global commitment amongst regulatory authorities to share clinical and safety data on H1N1 vaccines in real-time and to rapidly share information on any potential adverse events following immunization.

9. Where can I find more information?

Additional information on Arepanrix™ H1N1 can be found on the Health Canada and Public Health Agency of Canada websites. These websites will be updated as new information becomes available.

AREPANRIX™ H1N1 is a trademark of the GlaxoSmithKline group of companies.