

Issued: Wednesday 24 November, London UK

## **GSK Statement: Voluntary hold of Arepanrix (adjuvanted H1N1 pandemic vaccine) lot number A80CA007A in Canada**

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Following discussions with Health Canada, GlaxoSmithKline (GSK) has advised provincial and territorial health authorities, as a precautionary measure, to put on hold one lot of Arepanrix vaccines bearing the lot number **A80CA007A** until investigations being undertaken by GSK, Health Canada and the Public Health Agency of Canada (PHAC) have been completed.

GSK is committed to the highest standards of patient safety and care, and is taking this action as a result of a higher than expected rate of serious allergic reactions (anaphylaxis) related to this lot number compared to other lots. These observations have not been reported with vaccines from any other lots and therefore no other lots are impacted by this voluntary hold.

GSK continues to work with Health Canada to ensure that each vaccine lot released to the provinces and territories meets the highest quality and safety standards. The vaccination programme remains ongoing.

To date, approximately 15 million doses of Arepanrix have been distributed in Canada and, overall, the frequency of severe allergic reactions following immunisation is less than 1 event per 100,000 doses. This rate does not exceed the rates typically reported for other vaccines.

The vast majority of suspected adverse reactions reported to date in association with the vaccine have related either to the signs and symptoms of recognised side-effects listed in the product information. The most common side-effects reported in clinical trials were tiredness, headache, fever, joint/muscle pain, and swelling, pain, redness or a hard lump at the injection site.

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