MINISTRY OF HEALTH
SINGAPORE

HSA
Health Sciences Authority

Press Release

Voluntary Recall of Panvax® Junior H1N1 Vaccine

The Ministry of Health (MOH) and the Health Sciences Authority (HSA) would like to update the public on the voluntary recall of Panvax® Junior H1N1 vaccine (CSL Limited) in Singapore with immediate effect. The recall is a precautionary measure taken as a result of the findings by the Australia Therapeutic Goods Administration (TGA) on the decline in the potency of this product in Australia based on ongoing stability tests.

2 Panvax® Junior is CSL's 2009 H1N1 (pandemic) influenza vaccine, which is supplied in a single 0.25ml pre-filled syringe for administration to children between 6 months to less than 3 years.

3 There are no safety concerns with Panvax® Junior and parents or caregivers of children who have been vaccinated with this vaccine need not be alarmed. Panvax® Junior vaccine administered previously has adequate potency to induce an immune response. Children who require a second dose of Panvax® Junior can be vaccinated with the 2010 seasonal influenza vaccine.

Background information

4 HSA was informed today by Australia TGA that the stability testing results of certain units of Panvax® Junior vaccine in Australia showed a decline in the potency of the product. Based on these results, the registered shelf life of 12 months has been reduced to 6 months. CSL Limited has undertaken a voluntary withdrawal of all remaining Panvax® Junior vaccine in Australia.

5 CSL Limited has confirmed that there is no decline in potency of the Panvax® Junior supplied to Singapore. Nonetheless, as a precautionary measure, MOH is initiating a recall of existing Panvax® Junior H1N1 vaccine in Singapore. The safety of the vaccine is not affected.

6 The shelf life of pandemic vaccines as in the case of all other seasonal influenza vaccines is based on stability tests. To ensure that the potency of the vaccine remains within the specified shelf-life, manufacturers conduct ongoing stability studies throughout the recommended shelf life of the product. This approach is currently used by all of other regulatory agencies such as the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Australia Therapeutic Goods Administration (TGA) and Health Canada.

Local situation

7 About 1200 units of Panvax® Junior have been supplied to the hospitals and clinics locally since January 2010. The distribution of Panvax® Junior has been stopped and all remaining stocks will be recalled from affected clinics. Healthcare professionals have also been advised to cease administration of Panvax® Junior H1N1 vaccine with immediate effect.

8 To date, HSA has not received any adverse event reports related to a decline in potency of Panvax® Junior H1N1 vaccine administered in Singapore.

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