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H1N1 pandemic update on paediatric data for Pandemrix

The European Medicines Agency (EMA) today provided an update on the ongoing pharmacovigilance programme for the three approved H1N1 vaccines in Europe, reaffirming the safety profile of all authorised vaccines.

Over 39 million doses of GSK's *Pandemrix* have been distributed in Europe, representing the majority (~ 75%) of the total European supply of H1N1 vaccine to date.

As part of the update on GSK's *Pandemrix*, the EMA communicated that new clinical trial data in infants from 6 months to 35 months showed a greater incidence of fever following the second dose of *Pandemrix* than had been observed post dose one. These clinical data represent a preliminary, interim analysis on a sample size of 51 infants in an ongoing paediatric study. Additional data from this and other trials will be available shortly.

In addition, GSK and the EMA will continue to review and monitor the safety profile of *Pandemrix* as additional clinical trial and pharmacovigilance data become available.

Pandemrix should be used in line with the labeling information and publicly available national recommendations. Across Europe the recommendation for the administration of a second dose varies by country.

As stated by the EMA, the benefit/risk profile of *Pandemrix* in infants remains unchanged. To date, no unexpected serious safety issues have been identified. Worldwide, we estimate that almost 18 million doses of GSK's H1N1 vaccines have been administered in 26 countries.

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