

Novartis confident in safety and efficacy of its influenza vaccines

24 April 2013 | News | By BioSpectrum Bureau

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Singapore: Novartis has confirmed its confidence in the safety and efficacy of its seasonal influenza vaccines Agrippal and Flud manufactured in Italy.

Patient safety is of the highest priority to Novartis. Novartis internal assessments and the clinical data gathered during the 2012-2013 seasonal influenza studies required for European licensure of Agrippal and Flud demonstrate a safety and immunogenicity profile similar to that of prior years. To date, data from the ongoing seasonal vaccination campaign have revealed no safety signals.

The Italian ministry of health took this precautionary measure following a report by Novartis of small particles in the vaccines. Recently, Novartis voluntarily provided the Italian health authorities with its assessments supporting the quality, efficacy and safety of the specific vaccines in question. Novartis confirms that these particles can occur in the vaccine manufacturing process and is confident that there is no impact on the safety or efficacy of the vaccine.

The company will continue to work with the Italian Ministry of Health and AIFA to understand the reasons for their decision and to clarify any questions. The company is fully committed to providing high quality vaccines to patients and will continue to work with the authorities to make vaccines available.