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GSK European regulatory update on Pandemrix™

GlaxoSmithKline (GSK) today confirmed that on behalf of the European Medicines Agency (EMA), the Committee for Medicinal Products for Human Use (CHMP) has reviewed the interim report issued by the Finnish National Institute for Health and Welfare (THL) on their investigation into reported cases of narcolepsy in Finland. The CHMP has concluded that the data are still insufficient to establish a causal relationship between *Pandemrix* and narcolepsy and that no changes to the recommendations for use of *Pandemrix* are proposed. Further analyses and study results are awaited to clarify the observations in Finland.

GSK is committed to patient safety and will continue to work closely with EMA and other national regulatory organisations, providing information on any narcolepsy cases being reported to the company and other information they may request.

In addition to the work being done by GSK, the broader EMA investigation continues and includes an epidemiological study of narcolepsy and pandemic vaccines conducted by a network of research and public health institutions (VAESCO) in nine European Union Member States. GSK will also submit the final protocols for two additional case-controlled studies (in the UK and in Canada) to EMA in March 2011. The CHMP considered that more data need to be gathered to further assess the Finnish situation, as other non-Nordic countries have not seen similar increased rates of reporting of narcolepsy.

Over 31 million doses of *Pandemrix* have been administered worldwide in 47 countries. A total of 167 cases of narcolepsy in people vaccinated with *Pandemrix* have been reported to GSK as of 7 February 2011; with the majority of these cases of narcolepsy originating from Finland and Sweden.

GSK believes it would be premature to draw any conclusions on a potential likelihood of a causal relationship between *Pandemrix* and narcolepsy until the ongoing European investigation has been completed.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

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