

## **Merck responds to questions about Gardasil**

- 1) Is Merck conducting any studies to see if there are any patterns among the 30,000 people who have reported reactions to Gardasil?

As mentioned above, safety of GARDASIL has continued to be evaluated in several large post-licensure surveillance studies in more than 500,000 people following administration of more than a million doses of vaccine.

There is information on US surveillance and studies on the CDC website, which includes results from a large post-licensure study Merck conducted with Kaiser Permanente.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6229a4.htm?s\\_cid=mm6229a4\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6229a4.htm?s_cid=mm6229a4_e)

Here is the link to the WHO statement on safety from June 2013 that I mentioned above:

[http://www.who.int/vaccine\\_safety/committee/topics/hpv/130619HPV\\_VaccineGACVSstatement.pdf](http://www.who.int/vaccine_safety/committee/topics/hpv/130619HPV_VaccineGACVSstatement.pdf)

Merck conducts routine and ongoing monitoring of post-marketing adverse events for all medicines and vaccines as part of its ongoing commitment to patient safety. Merck communicates proactively to regulatory agencies, health care providers – and often parents and patients directly – to provide timely and comprehensive information about the safety and efficacy of our products. We also update the labeling for our products on a regular basis and where appropriate to reflect reported adverse events, regardless of whether causality has been established.

- 2) Does Merck have an agreement with GlaxoSmithKline (manufacturer of an alternative HPV vaccine) to share profits/give a percentage of revenue from each shot?

As is common in breakthrough fields of research, a number of scientists at many institutions made significant contributions to the discovery of virus-like particles that led to GARDASIL. Therefore, the Company is a party to certain third-party license agreements with respect to GARDASIL (including a cross-license and settlement agreement with GlaxoSmithKline). As a result of these agreements, the Company pays royalties on worldwide sales of GARDASIL.

- 3) Are there people who are not good candidates for Gardasil?

The labeling for GARDASIL (Patient Information and Prescribing Information for healthcare providers) includes this information. Here is a link to both.

[http://www.merck.com/product/usa/pi\\_circulars/g/gardasil/gardasil\\_ppi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_ppi.pdf)  
[http://www.merck.com/product/usa/pi\\_circulars/g/gardasil/gardasil\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf)

- 4) How long does the vaccine actually protect people for?

The Prescribing Information contains information from clinical studies through 5 years, and notes that the duration of protection with GARDASIL has not been established. Merck continues to evaluate long-term effectiveness. Recently there were data presented at the EUROGIN Congress in November; see Abstract OC 6-3 on page 201 of the attached PDF (also available via this link) for data from a study being conducted in the Nordic region.

<http://www.eurogin.com/2013/images/pdf/EUROGIN-2013-Abstracts-Part-2.pdf>