

Steve Hinks
request-195787-b1bde6c6@whatdotheyknow.com

MHRA
151 Buckingham Palace Road
Victoria
London SW1W 9SZ
United Kingdom

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4th March 2014

Dear Mr Hinks,

Thank you for your email dated 3rd February 2014 requesting information regarding questions around the HPV vaccine.

Please see the below response.

“- why 1 report per 1000 doses administered was not considered unexpected (this is 300 reports per 100,000 recipients, which is HUGE compared with other vaccines which typically have EER per 100,000 recipients ranging from 0.8 to 14)”

This statement refers to the overall Yellow Card reporting rate for Cervarix vaccine. Prior to implementation of the Cervarix campaign in September 2008, MHRA anticipated receiving a reporting rate at a level at least as high as that seen when meningitis C conjugate vaccine was first introduced in the UK in 1999 (Reference document - see page 10 of <http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con096797.pdf>). The UK was the first country to use the meningitis C conjugate vaccine. At that time, we received almost 13,000 Yellow Cards following distribution of around 18 million doses of vaccine, equating to a reporting rate of around 0.7 reports per 1,000 doses distributed (data on doses actually administered were not available when this was calculated) (Reference documents- <http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con2022528.pdf>).

However, unlike when meningitis C vaccine was first introduced, by 2008 the general public were included as reporters to the Yellow Card Scheme and there was better access to the Scheme via on-line reporting. Taking this into account, the overall reporting level of 1 per 1,000 doses of Cervarix administered was not considered unexpected for a major new immunisation campaign.

“- why this immunisation programme is considered to be novel.”

Although Cervarix had already been marketed in some countries, the UK was the first country to undertake a major routine immunisation campaign with Cervarix and the vaccine contained a new proprietary adjuvant. This is why it was described as novel in the context of this statement.

Kind Regards,

FOI Team
MHRA