

Response from Medsafe – New Zealand

From: stewart_jessamine@moh.govt.nz [mailto:stewart_jessamine@moh.govt.nz]

Sent: Wednesday, 28 September 2011 5:02 p.m.

To: Hilary Butler

Subject: Re: Alleged Gardasil contamination.

Dear Ms Butler

Thank you for your e-mail concerning alleged contamination of Gardasil vaccine.

Medsafe considers the benefits of Gardasil vaccination outweigh the risks.

Medsafe does not sign confidentiality agreements with third parties as these would make it impossible for Medsafe to perform its role in protecting public health. If you have, or are aware of data that would change the balance of risks and benefits of any medicine, Medsafe would expect that this would be made available for Medsafe's immediate review.

The presence of recombinant DNA fragments in Gardasil vaccine does not indicate that the vaccine has been contaminated. All medicines manufactured using recombinant technology may contain fragments of recombinant DNA. These DNA fragments are not considered to cause a risk to people who have received the vaccine as these fragments are unable to replicate or cause infections. The safety profile for Gardasil does not indicate any cause for concern at the present time.

Medsafe considers that the information provided about the current allegations make no material difference to what is known about the quality of this vaccine. This is a view shared by other regulatory authorities, including the European medicines regulatory authority (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/09/WC500112851.pdf).

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