

Newsletter 8: The TGA's Reply

17 November 2012

In my last email I informed you that the TGA did not reply to the questions I asked about the HPV vaccine in August 2011. Two days after this email was sent (6th Nov 2012), I got a reply from the TGA which I will publish on my website in the letters menu (Publications page). This letter did not answer any of the questions we are asking. I have written a reply to the TGA that I will present to you here and I hope that you will pass this on so we can be sure that this policy is based upon evidence. Here is my reply to the TGA:

To the Therapeutic Goods Administration (TGA)

RE: My reply to the TGA re Questions about HPV vaccine (August 2011)

Dear Debbie (**no surname provided**),

Thankyou for replying to my letter, however you have not answered any of the questions that consumers are asking about this vaccine. The TGA continues to state that: **'the HPV vaccine is safe and effective and the benefits of the vaccine outweigh its risks' – without providing evidence.**

Consumers would like to believe this message but they are looking for **evidence** and it is not provided in the TGA-approved Product Information (PI) that you suggested could be found by searching the TGA website. Please could you provide the answers to the questions I asked previously (August 2011) and which I will summarise for you here:

1. This vaccine has not been demonstrated to prevent any cervical cancer so why is it being promoted as a cervical cancer vaccine and not an HPV vaccine?
2. If the majority of pre-cancerous lesions in 16 -26 year old women clear without medical treatment and are not an indication of cancer later in life (as the Australian Government states) how can this end-point (pre-cancerous lesions) be used as an indication of the number of cervical cancer cases that will be prevented by using this drug? This was the end-point used in the clinical trials.

3. How could the clinical trials make an accurate estimate of the harm this drug will cause when the placebo that was used in the 'unvaccinated' group was the **aluminium adjuvant in the vaccine** (aluminium hydroxyphosphate sulphate)? – a chemical that is known to be linked to delayed reactions including autoimmune diseases and hypersensitivity.
4. Why does this vaccine contain sodium borate (pesticide) and polysorbate 80 – both known to cause infertility in laboratory rats?
5. Can a 'passive' monitoring system such as that used by the TGA allow the regulator to make causal links between adverse events (AE's) and the HPV vaccine? This system relies on voluntary reporting - how can you determine the frequency and cause of events if you are not 'actively' following up all health outcomes of vaccinated people for a period of about 5 years?
6. If women vaccinated with HPV vaccine can still get cervical cancer (*because of the other 13 causal subtypes of HPV that are not covered by the vaccine*) **and** if the vaccine has not been proven more effective than Pap screening combined with LEEP (the procedure used to remove abnormal cells) **then why are women and school children not being informed of this so they can decide for themselves if they want to risk the side-effects of this drug?**

These are the questions that many consumers would like the TGA, the PHAA or Professor Ian Frazer to answer. I will publish your reply on my website with these questions and I hope that you will answer them before this vaccine is used in boys and girls in schools in 2013.

I will also provide 2 links that indicate the serious harm that this vaccine is causing to an *unknown* percentage of the population. You can also find more examples of this harm at www.sanevax.org .

Here is a link to Kristin Clulow who was seriously affected by HPV vaccine several years ago:

<http://www.abc.net.au/news/2012-08-27/newcastle-woman-raises-concerns-about-cervical-cancer-vaccine/4224152?microsite§ion=news>

Here is a link to a report in the British Medical Journal (BMJ) of a young girl who has become infertile at 16 after being given the HPV vaccine:

[BMJ Case Reports 2012; doi:10.1136/bcr-2012-006879](https://doi.org/10.1136/bcr-2012-006879)

I look forward to your prompt reply to these questions.

Kind regards,

Judy Wilyman

www.vaccinationdecisions.net