Office of Hon Dr Jonathan Coleman
Minister of Health
Minister for Sport and Recreation
Member of Parliament for Northcote

29 SEP 2017

Virginia Crawford
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Ref: H201703556

Dear Ms Crawford

Response to your request for official information

Thank you for your request of 30 August 2017 under the Official Information Act 1982 (the Act) for:

> **'The package inserts for Gardasil, published by the FDA and Medsafe NZ, list possible adverse events that may be experienced as a result of this vaccine.**
>
> **FDA version: https://scanmail.trustwave.com/?c=5305&d=3t-n2WRai5nhKQ4ghiWgwqh3A6y40Ph403J13xwPHQ&u=https%3a%2f%2fwww%2efda%2egov%2fdownloads%2fbiologicsbloodvaccines%2fvaccines%2fapprovedproducts%2fucm426457%2epdf**
> **Medsafe version:**
> **http://www.medsafe.govt.nz/profs/datasheet/g/gardasil9inj.pdf.**
>
> **However several events are missing from the New Zealand version. These are as follows:**
> **Blood and lymphatic system disorders: Autoimmune hemolytic anemia.**
> **Respiratory, thoracic and mediastinal disorders: Pulmonary embolus.**
> **Gastrointestinal disorders: Pancreatitis.**
> **Immune system disorders: Autoimmune diseases.**
> **Nervous system disorders: motor neuron disease, paralysis, seizures.**
> **Vascular disorders: Deep venous thrombosis**
> **General disorders and administration site conditions: DEATH**
>
> **I'm sure you will agree that these are pretty serious omissions. The Parent Consent Form, used in the school based vaccination program, is a very watered down version of the package insert (with even less real information about side effects), so parents really have no idea of what risks their children might be facing.**
>
> **Parent Consent Form: https://scanmail.trustwave.com/?c=5305&d=3t-n2WRai5nhKQ4ghiWgwqh3A6y40Ph40yB4hBENHA&u=https%3a%2f%2fwww%2ehealthed%2egovt%2enz%2fsystem%2ffiles%2fresource-**

files%2fHE2044%5fHPV%5fVaccine%5fParent%5fConsent%5fForm%2epdf
Further information for parents:
http://www.medsafe.govt.nz/consumers/cmi/g/gardasil9.pdf

Are you aware of these anomalies?

Will you investigate the reasons for these adverse events to be kept hidden from the New Zealand public?

Will you make sure that the situation is put right?"

Gardasil 9 is approved for use and publicly funded in New Zealand because its benefits far outweigh the small risks associated with its use. Note that the first HPV-vaccine was quadrivalent Gardasil. However, information about quadrivalent Gardasil also applies to Gardasil 9. HPV-related cancers kill more than 50 New Zealanders every year and the majority of these deaths are vaccine-preventable. Significant amounts of research, both before and after Gardasil and Gardasil 9 were first approved, have shown no association between the vaccine and a range of serious illnesses.

You have noted that the product information for Gardasil is different between the US and New Zealand. Please note that the list of adverse events for Gardasil in the New Zealand Data Sheet is the same as the product information for Gardasil in Australia and in the European Union.

Consent forms are written to ensure they are as widely understood as possible. The information in the parent consent form sets out common reactions to the vaccine as well as anaphylaxis, a known rare but serious reaction. For those readers who would like more information, it suggests a number of additional sources, including Medsafe's Consumer Medicine Information and Data Sheet. This is consistent with other countries' practices in seeking consent for vaccines administered in schools.

The differences that you mention between the New Zealand Data Sheet and the US product information are contained in the post-marketing experience section. Determining whether there is a link between an event which occurs outside of a clinical trial and a medicine (including vaccines) is difficult. Many other factors such as other diseases or other medicines may have contributed to the event. This section is open to interpretation and can vary in different countries.

I will provide a brief summary of the reasons why these events are not included in the New Zealand product information.

Medsafe has published data regarding four reports of death in people who had been vaccinated with Gardasil. No link was found with Gardasil after investigation: www.medsafe.govt.nz/publications/OIA/22SeptDeathsFromGardasil.pdf

Medsafe, in conjunction with the Medicines Adverse Reactions Committee (MARC), evaluated the potential side effect of autoimmune diseases with Gardasil in 2015. This review included all types of autoimmune diseases including autoimmune haemolytic anaemia. The conclusion of the review was that there is no safety concern relating to the

development of autoimmune conditions and Gardasil vaccination: www.medsafe.govt.nz/profs/adverse/Minutes163.htm

Information from many sources are used when safety of medicines and vaccines used in New Zealand are monitored. This includes studies and other published medical literature, information from other regulatory authorities as well as pharmaceutical companies, and spontaneous suspected adverse reaction reports submitted to the Centre for Adverse Reactions Monitoring (CARM). With regard to the other mentioned events there have been no safety concerns highlighted and no reported cases of pulmonary embolus, deep vein thrombosis, pancreatitis, or motor neuron disease in people given Gardasil in New Zealand. Therefore Medsafe has not evaluated these events and they are not mentioned in the data sheet.

Eight reports of seizures have been reported in New Zealand. On review, these reports were considered to represent cases of 'syncope sometimes accompanied by tonic-clonic movements' (as described in the Data Sheet). There was one exception where the patient was known to be epileptic. One case of paralysis was reported in someone who also had muscle aches. One case was not considered to represent a safety problem that should be included in the Data Sheet.

You can find more information on how Medsafe investigates safety concerns at www.medsafe.govt.nz/safety/safety-monitoring.asp

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my response to your request.

Yours sincerely

Peter McCardle
Senior Ministerial Advisor
Office of the Minister of Health