From: QHIP-ADMIN QHIP-ADMIN [mailto:QHIP-ADMIN@health.qld.gov.au]
Sent: Friday, 7 October 2011 1:04 PM
To: Stephen Tunley
Subject: Gardasil vaccine

MO11004696
MI177552

Dear Mr. Stephen Tunley

STunley@balmain.com.au

Dear Mr Tunley

Thank you for your email of 5 September 2011, regarding Gardasil vaccine. The Minister has asked that I respond on his behalf.

Please note the following information regarding regulation of vaccines in Australia, and specific information on Gardasil vaccine safety:

Regulation of Vaccines

In Australia, vaccines and other prescription medicines are regulated by the Therapeutic Goods Administration (TGA) in accordance with the provisions of the Therapeutic Goods Act 1989 (the Act). It is a requirement of the Act that therapeutic products imported into, supplied in, or exported from Australia be included in the Australian Register of Therapeutic Goods (ARTG).

In order for a vaccine to be included in the ARTG, a sponsoring company is required to make an application which consists of data to support the quality, safety and efficacy of the product for its intended use, and which is then subject to rigorous evaluation by the TGA. TGA's data requirements are largely based on those applying in the European Union, supplemented by Australia-specific requirements where necessary. Extensive guidance is available to assist with the interpretation of the requirements, including documents relating specifically to the registration of vaccines.

The quality control aspects of an application cover the batch production processes to ensure that the medicine is produced to a consistent standard as defined by the product specification. This quality specification places controls on the purity and potency of the medicine as well as on other aspects necessary to ensure the efficacy of the product.

Recognising the important role of vaccines for public health, the pre-market quality review of vaccine submissions is supplemented by a batch release program operated by TGA in accordance with recommendations of the World Health Organization. Through this program, production and quality control data for each batch of a vaccine are assessed prior to it being supplied in Australia. The TGA also operates a batch testing program for the most widely used vaccines, including influenza vaccines, in which aspects such as the potency and sterility of the vaccine are checked.

The pre-clinical data supplied to TGA for assessment include studies designed to assess the toxicological profile of the medicine.

The third component of an application to include a vaccine, or other prescription medicine, in the ARTG is the submission of clinical data. This part of a submission consists of clinical trial data in humans. These data are used to support both the safety and efficacy of the product for the indications proposed by the product sponsor. The clinical data requirements vary with different products and different types of submission. In general, well-designed trials conducted in a sufficient number of subjects representing the target population and of a sufficient duration are usually required in order to demonstrate the efficacy and safety of the product for the proposed indication. The clinical evaluators assess the balance of benefits and risks based on the submitted clinical trial data and then recommend approval or rejection of the application based on that overall assessment. Each medicine and vaccine carries the risk of adverse effects in some people; the key issue in the regulatory decision is to determine that the overall balance of risks and benefits is positive in the population in whom the product is intended to be used.

Since April 2009, the TGA has required sponsors to submit a formal risk management plan (RMP) with each application for registration or extension of indication of a new medicine or vaccine. RMPs are intended to set out those activities and interventions that will be undertaken to identify, characterise and mitigate known or anticipated risks relating to a new medicine or vaccine, recognising that premarketing trials cannot prospectively identify all safety issues.

Gardasil vaccine

Gardasil is manufactured using recombinant DNA technology so any finding of residual DNA fragments in the vaccine is expected and does not represent contamination.

Residual HPV LI DNA (the relevant DNA) fragments in the vaccine are present in such small quantities that the manufacturer cannot measure it using a PCR assay but can only estimate the quantity.

There have been large post market studies of Gardasil including a study released this year of 189,000 US women who were immunised with Gardasil and the adverse event profile does not raise any safety concerns apart from a small incidence of anaphylaxis (which was already known). These population studies have not uncovered any concern about elevated rates of auto-immune disorders or rheumatoid arthritis

Australia was one of the first countries to roll out a national cervical cancer immunisation campaign using Gardasil.

As at June 2010 more than 6 million doses of Gardasil have been distributed in Australia. The overall number of suspected adverse events reported following Gardasil administration is very low, and consistent with other new vaccines and adverse event rates reported in other countries. Worldwide, over 61 million doses have been distributed.

No vaccine is completely without side-effects, and so adverse events following immunisation are carefully monitored in Australia and regularly reviewed by expert advisory groups. A significant volume of reporting of adverse events is often seen shortly after the introduction of a new, widely-used vaccine because of the higher degree of vigilance and lack of familiarity with the new product. Many of the reported events (such as headache, feeling dizzy or unwell) may be equally common in people of the same age who have not received the vaccine.

No deaths directly linked to the vaccine have been reported in Australia, the USA or Europe.

In addition to assessing Australian adverse event data, the TGA continues to evaluate all available safety information on Gardasil, including analyses from the United States Vaccine Adverse Event Reporting System and studies from the Vaccine Safety Datalink project. Worldwide reports of rare adverse events such as pancreatitis and neurological adverse events will continue to be monitored closely. Through ongoing contact with overseas regulatory agencies the TGA will continue to monitor the occurrence of any serious events related to the use of Gardasil anywhere in the world.

In addition to the TGA, both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) have assessed Gardasil as safe and effective.

The National HPV Vaccination Program is part of the National Immunisation Program and an important strategy in the prevention of cervical cancer in women. Queensland Health is committed to implementing this program and continues to work towards improving uptake of vaccine in the target group.

Thank you for bringing this to the Minister's attention.

Yours sincerely

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