Community Affairs Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Inquiry into Social Services legislation Amendment (No Jab, No Pay) Bill 2015

Monday, 2 November 2015

Question no: 1

Topic: Effectiveness of whooping cough vaccine

Type of Question: General Information

Senator: Senator Moore

Question:

Can the Department please provide details of the effectiveness of the whooping cough vaccine?

Answer:

The first whooping cough, diphtheria-tetanus-acellular pertussis (DTPa), vaccine was registered in Australia in 1996 and the vaccine has been nationally funded since 1999.

While no vaccine is 100% effective, a high rate of immunisation helps to maintain herd immunity. Pertussis vaccines provide good protection against severe and typical pertussis, however substantially less protection against milder coughing illness. While the vaccine may not protect an individual from becoming infected with a mild case of whooping cough, it will protect them from getting a severe case of the disease, resulting in less hospitalisations for pertussis.

Vaccine efficacy ranges from 71 to 78% for preventing milder symptoms of pertussis; and 84% for preventing severe disease. The incidence of severe pertussis is reduced after an infant receives its first dose of the vaccine (at six-eight weeks), with maximum protection provided when all doses in the vaccine schedule are received.

Topic: Serious Adverse Event Reports

Type of Question: Data

Senator: Senator Moore

Question:

Can the Department please provide the number of serious adverse events reported over a period of time by vaccine type and age group?

Answer:

Within the time frames available for this response, the Therapeutic Good Administration (TGA), is only able to provide data on serious adverse event reports spanning a five year period from 1 July 2010 to 30 June 2015, for children under five years of age. This aligns with the age range upon which the definition of fully immunized (for the purposes of vaccination coverage reporting from the Australian Childhood Immunisation Register, from which the fully immunised status will be generated) for the no jab, no pay measure.

The TGA definition of a serious adverse event, in relation to this data, is any report of hospital admission, life threatening illness, or death.

The total number of serious adverse events following immunisation (AEFI) reports, received by the TGA, for children under the age of five years across five years, and approximate percentage rate of serious adverse events based on total number of children vaccinated is as follows:

Financial year	**2010-11**	**2011-12**	**2012-13**	**2013-14**	**2014-15**
Children < 5	100	64	66	75	80*
**Percent rate of serious adverse events	0.000093%	0.000059%	0.000061%	0.000069%	0.000074%

***Note:** the 243 serious adverse event reports advised by Ms McNeill at the Senate hearing related to the data provided by the TGA on all serious adverse event reports across all vaccines administered in Australia across all age groups.*

**BASED ON ABS DATA, THE AVERAGE NUMBER OF CHILDREN IN THE INDIVIDUAL COHORTS IS 300,000. INCLUDING THE FOUR COHORTS 0-1, 1-2, 2-3, 3-4, THE TOTAL NUMBER OF CHILDREN IMMUNISED PER YEAR IS 1.08 MILLION, ASSUMING 90% COVERAGE.

Over this period five of the serious adverse event reports were related to a death, however, it is important to note that an AEFI report does not imply causality. It is also important to note that the total number of serious adverse events in children below the age of five years is for all vaccines administered within Australia, not just vaccines provided under the National Immunisation Program.

The five year breakdown of serious AEFI reports by vaccine type and age is provided in the following table. It is important to note that the total number of serious adverse events and the numbers reported for each age group are not equal, because a single adverse event report may relate to multiple vaccines, either co-administered vaccines and/or vaccines administered separately within a day or two of each other.

Financial year	2010-11	2011-12	2012-13	2013-14	2014-15
Hepatitis B					
Under 1 year	6	4	0	0	2*
Hep B-DTPa-Hib-IPV					
Under 1 year	59	46	48	55	60
Pneumococcal conjugate (13vPCV)					
Under 1 year	0	35	35	53	57
Rotavirus					
Under 1 year	73	49	58	59	67
HiB – Men C					
Under 1 year	0	0	0	1	1
1-2 years	0	0	0	13	14
3-4 years	0	0	0	0	0
Influenza					
Under 1 year	0	0	0	0	1
1-2 years	11	2	4	0	1
3-4 years	2	2	2	3	4
Meningococcal B					
Under 1 year	0	0	0	0	3
1-2 years	0	0	0	0	2
3-4 years	0	0	0	0	0
BCG					
Under 1 year	0	1	0	1	1
1-2 years	0	0	0	1	1
3-4 years	0	1	0	0	0

** **Note:** Ms McNeill advised of no serious adverse events reports for Hepatitis B in 2014-15 to the Senate hearing, however, two reports were identified when TGA re-ran the data report in response to these Questions on Notice. Previous data reports from TGA data base did not include any adverse events for Hepatitis B because the report only generated data above a minimum ten reports.*

Topic: Vaccine Safety

Type of Question: General Information

Senator: Senator Moore

Question:

Can the Department please provide an overview of the Therapeutic Goods Administration (TGA) registration assessment process for vaccines to determine safety, quality and efficacy, including a description of the process for assessing the safety of combination vaccines?

Answer:

The TGA is responsible for the regulation of therapeutic goods, including vaccines, in Australia. It is a general requirement under the *Therapeutic Goods Act 1989* that vaccines to be imported into, supplied in, or exported from Australia be included in the Australian Register of Therapeutic Goods.

For a vaccine to be marketed in Australia, a sponsor must submit an application to the TGA accompanied by scientific and clinical data to support the quality, safety and efficacy of the vaccine for its intended use.

In terms of assessing the safety of combination vaccines, the TGA assesses all data in the studies provided to the TGA (by the sponsor). In the submitted studies, the combination vaccine is administered as a whole vaccine, so the safety assessment is for the vaccine as a whole. The common safety parameters include local adverse events (such as local pain), systemic adverse events (such as fevers), any serious adverse events, any discontinuation from the trial, and any death. When assessing the immune responses of a combination vaccine, the antibody response to each individual antigen (included in the combination vaccine) is also measured and assessed.

The TGA undertakes thorough evaluation of the data and will usually seek the advice of an independent expert advisory committee, before making a decision to approve or reject a new vaccine.

Once approved, every batch of vaccine is reviewed by the TGA prior to release. This review may include laboratory testing, which provides independent assurance of the statements of the manufacturer.

To further ensure the continued safety of the Australian public, the TGA undertakes post-market monitoring of approved vaccines. The primary focus of this work is to capture and investigate safety issues and to ensure vaccine sponsors have appropriate mechanisms in place to identify safety concerns that may arise once a vaccine is marketed in Australia.

In recent years, improvements to the surveillance of adverse events following immunisation have been implemented by the TGA in consultation with the jurisdictional health authorities. These improvements have included more timely arrangements for sharing adverse event reports between the jurisdictions and the TGA, and the review of all vaccine adverse event reports within the TGA.

The TGA publishes information about adverse events associated with vaccines on its website. The Database of Adverse Event Notifications (DAEN) contains information from reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia. The DAEN is publicly available via the TGA website at http://www.tga.gov.au/database-adverse-event-notifications-daen.

The TGA also works very closely with its international counterparts to make sure they have access to the latest safety information and, where required, take appropriate regulatory actions in collaboration with their international counterparts.

Topic: Safety of Gardasil vaccine

Type of Question: General Information

Senator: Senator Moore

Question:

In relation to the Gardasil vaccine can the Department please provide an overview of the international perspective?

Answer:

Gardasil has been approved within Australia and the United States since 2006. Within the same period, over 120 countries worldwide have endorsed and recommended the vaccine for administration to prevent human papillomavirus associated cancers and genital warts.

Worldwide, drug regulators including the Therapeutic Goods Administration (TGA) (Australia), the Food and Drug Administration (USA), the Medicines and Healthcare Products Regulatory Agency (United Kingdom) and the European Medical Agency (European Union countries) all considered the HPV vaccine to be safe and effective, and continue to support the recommended use of the HPV vaccines.

In March 2014, the World Health Organisation's Global Advisory Committee on Vaccine Safety (GACVS) published a 'statement on the continued safety of HPV vaccination' (Attachment A). The GACVS has not found any safety issue that would alter any of the current recommendations for the use of HPV vaccines, including Gardasil.

Following the GACVS published recommendations, the Center for Strategic and International Studies published the HPV vaccination in Japan (Attachment B). The paper outlines the safety concerns expressed and recommends that Japan reinstate an active government promotion of the HPV vaccination along with carefully considered public communication campaigns. Evidence to support this recommendation includes statistics on the vaccine's safety and the successful implementation and high uptake rates of the vaccine in other countries.

The Australian Immunisation Handbook (10th Edition) states that, for both HPV vaccines on the market, the most common reported adverse events are mild in nature and include injection site pain, followed by swelling and erythema along with headache, fatigue, fever and myalgia. Findings from clinical HPV vaccine trials have shown there is no increase in the risk of a serious adverse event in those who have received the HPV vaccine compared to those who have not.

The Advisory Committee on the Safety of Vaccines (ACSOV) has twice, in October 2013 and again in December 2014, considered the issue of premature ovarian failure, a condition now termed premature ovarian insufficiency (POI), following Gardasil vaccination. The Committee's advice was that there is no biologically plausible explanation for POI following Gardasil vaccination, the limited epidemiological data did not support an association linking POI and Gardasil and there was no signal of a causal association for POI following administration of the vaccine. Since the Committee last reviewed the issue, no new information to change this advice has been identified. Safety monitoring of Gardasil is continuing in Australia and globally.

In the context of the Public Hearing to the proposed Social Services Amendment (No Jab, No Pay) Bill 2015, and the committees concerns, the Department of Health clarified on *the Hansard* that the HPV vaccine was not in scope for the proposed legislative amendments as HPV vaccines are given to 12-14 year olds and the proposed 'No Jab, No Pay' policy relates to vaccines included in the early childhood schedule only.

National Immunisation Program schedule for the No Jab No Pay Measure

Vaccinations* included in the No Jab, No Pay measure are diphtheria, tetanus and pertussis (DTP), measles, mumps and rubella (MMR), polio, hepatitis B, haemophilus influenzae type b (HiB), meningococcal C and varicella.

The definition of fully immunised for the purposes of vaccination coverage reporting from the Australian Childhood Immunisation Register (ACIR), from which fully immunised status will be generated, includes immunisation against:

1 year olds - DTP, polio, hepatitis B, Hib, and pneumococcal.
2 year olds - DTP, polio, hepatitis B, Hib, MMR, meningococcal C, and varicella.
5 year olds - DTP, polio, and MMR.

*Please note that for the purposes of the catch-up vaccines for older children, not all of the above vaccines may be required, depending on the date of birth of the child.

Topic: National Immunisation Program public communications

Type of Question: General Information

Senator: Senator Moore

Question:

Can the Department please provide a detailed account of all public communications around the National Immunisation Program, including budget allocations and materials related to the no jab, no pay measure?

Answer:

General approach to immunisation communications
The objective of the National Immunisation Program (NIP) is to ensure Australia continues to maximize national immunisation coverage to successfully reduce the incidence of vaccine preventable illnesses across the Australian community. The National Immunisation Strategy for Australia 2013-2018 sets out action areas to maintain the successful delivery of the NIP. The Department provides communications to the public, including health professionals, on the Immunise Australia Program to maintain and ensure community confidence in the NIP.

Immunise Australia website
The Department of Health maintains and updates the Immunise Australia website http://www.immunise.health.gov.au/ which provides accurate, up to date and evidence-based resources and information about the NIP, which can be ordered or downloaded. Resources and information is targeted at a range of audiences, including health professionals, individuals and families.

Resources for health professionals include:

- publications such as *The Australian Immunisation Handbook, and Myths and Realities: Responding to arguments against vaccination*; and
- other resources, such as Commonly Observed Reactions to Vaccination tear off sheets and Strive for five vaccine storage advice posters; and
- a range of other vaccine-specific posters, brochures and fact sheets on the introduction of a new vaccine, schedule point or program.

In addition, the Department provides information to vaccination providers and consumers about a new vaccine or schedule point, including materials to promote uptake. In 2015, the Department provided information on the Immunise Australia website, as well as via a mail out to vaccination providers, about the Seasonal Influenza Vaccination Program.

Resources to assist parents' understanding of the NIP include:

- Your Guide to Understanding Childhood Immunisation, which is provided to parents at childbirth;
- The NIP childhood schedule poster and card to remind parents of key vaccination timings; and
- a range of fact sheets to promote the importance of vaccination for parents.

The Immunise Australia website was refreshed and updated in April 2014 with improved functionality and usability to ensure information about immunisation is readily and easily available.

Recent budget announcements to reduce the incidence of vaccine-preventable diseases in Australia

The 2015-16 Budget included a number of measures relating to immunisation. These included the addition of two new vaccines on the NIP – a booster for 18-month old children for whooping cough (pertussis) and the National Shingles Vaccination Program - and the Improving Immunisation Coverage Rates measure to continue to improve national vaccination rates. The Improving Immunisation Coverage Rates measure included funding of $4.7 million over four years for a range of communication activities, tools and resources, underpinned by comprehensive market research, to increase awareness and understanding of the NIP and to address parents' concerns regarding immunisation. The market research will be undertaken in 2015-16 and will inform future immunisation communication activities.

Planned campaigns

40,000 NIP vaccination providers will receive detailed information about the new vaccine or schedule point along with promotional materials including posters, fact sheets and resources to assist with discussions with parents. Additionally, specific resources will be provided for Aboriginal and Torres Strait Islander populations.

No Jab, No Pay

The Department of Social Services has overarching policy responsibility for the Extending immunisation Requirements (No Jab, No Pay) measure and is leading communications with family benefit clients and stakeholders, including child care centres. The Department of Health is responsible for providing advice to vaccination providers on their role in giving catch up vaccinations under this measure.

In September 2015, the Department provided early advice to stakeholders, and will write to vaccination providers closer to the commencement of the program on 1 January 2016, subject to the passage of legislation. The letter will provide detailed information on the catch-up immunisation schedule, how to check a child's immunisation history, how to order vaccines and updating immunisation records.

Topic: Hepatitis B Vaccine website information

Type of Question: General Information

Senator: Senator Moore

Question:

What information does the Department have on its website about the Hepatitis B vaccine, including its safety and data on adverse events, and in particular its safety on newborn babies?

Answer:

The Immunise Australia website provides information about the hepatitis B vaccine at http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/immunise-hepb. Information is provided on the causes, symptoms and prevention of hepatitis B, and also directs visitors to:

- *The Australian Immunisation Handbook* online chapter on hepatitis B. This chapter provides detailed information on administration of the hepatitis B vaccine to infants from birth, and advice on adverse events. This chapter is available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home~handbook10part4~handbook10-4-5
- *The Understanding Childhood Vaccination* booklets which answer parents' commonly asked questions about vaccinating children. These booklets provide information on vaccine preventable diseases, including hepatitis B, vaccines, vaccine side effects and what to do if a child has a reaction after receiving a vaccination. The booklets are available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/IMM52-cnt

The Therapeutic Goods Administration (TGA) Database of Adverse Event Notification (DAEN), http://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx, allows you to search for adverse event reports for medicines and vaccines.

The Australian Public Assessment Reports on prescription medicines (AusPARs) provide information on the evaluation of prescription medicines (including vaccines) and the considerations that led TGA to approve or not approve an application.

The requirement for AusPARs was established in 2009, therefore, there is only information on vaccines/medicines after that date. General information about AusPARs can be found at: https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars

The AusPAR for the Hexaxim vaccine can be found at: https://www.tga.gov.au/auspar/auspar-haemophilus-type-b-polysaccharide-hepatitis-b-surface-antigen-pertussis-filamentous-haemagglutinin-pertussis-toxoid-poliovirus-tetanus-protein-tetanus-toxoid-diphtheria-toxoid

Report numbers on serious adverse events for this vaccine in children in the previous five financial years have been provided under question two.

Topic: Medical exemptions

Type of Question: General Information

Senator: Senator Moore

Question:

Please provide detailed information about what does and does not constitute a medical exemption for a vaccine.

Answer:

Medical exemptions for a vaccine fall into two categories, ongoing medical exemptions and circumstances where a vaccine can be temporarily deferred.

The medical basis for vaccine exemption is based on guidance in *The Australian Immunisation Handbook* (10th edition, 2013)
Ongoing medical contraindications include:

- anaphylaxis following a previous dose of the relevant vaccine;
- anaphylaxis following any component of the relevant vaccine; and
- significant immunocompromise, regardless of whether the immunocompromised is caused by disease or treatment (for example HIV or cancer treatment).

In addition, natural immunity to a disease is also a valid exemption to vaccination for the following vaccines:

- Measles
- Mumps
- Rubella
- Varicella
- Hepatitis B

Natural immunity must be confirmed via laboratory testing or a physician-based clinical diagnosis. Exemption to a combination vaccine/s on the basis of natural immunity is only valid if immunity is confirmed for all vaccine antigens.

There are some circumstances where vaccinations should be temporarily deferred. These include:

- acute febrile illness (current temperature $\geq 38.5^{o}$C) or acute systemic illness;
- significantly impaired immune function that is anticipated to be of short duration; and
- pregnancy (live attenuated vaccines only), and women should be advised not to become pregnant within 28 days of receiving a live vaccine.

No child should be denied the benefits of vaccination by withholding vaccines for inappropriate reasons. A comprehensive list of false contraindications to vaccination can be found in the *Australian Immunisation Handbook* (10th edition, 2013), and include:

- Egg allergy, even severe, is not necessarily a valid exemption for any vaccines routinely recommended for children.
- Mild illness including mild fever $<38.5^{o}$C is not a valid exemption to vaccination.

For the No Jab, No Pay measure, these guidelines for what does and does not constitute a valid medical exemption for a vaccine have been considered and a medical exemption form for medical practitioners to complete is being developed in consultation with the National Centre for Immunisation Research and Surveillance and other key stakeholders i.e. paediatricians.