

PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

# Walking the allergy tightrope

*Addressing the rise of allergies and anaphylaxis in Australia*

House of Representatives Standing Committee on Health, Aged Care and Sport

May 2020  
CANBERRA

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# Foreword

Australia has been called the world's 'allergy capital' because of the increases in rates of allergies and anaphylaxis over the last twenty years. Over four million Australians live with allergies, and for many it is a tightrope to walk every day. As there is essentially no cure for allergies, it has become a significant public health issue - highlighted by the long waiting lists for patients to see allergy specialists throughout Australia.

An allergy occurs when a person reacts to a substance in the environment that is harmless to most people. Humans can be allergic to any protein, but some of the more common allergens are found in dust mites, pets, pollen, insects, ticks, moulds, foods and medications. Anaphylaxis is the most severe form of allergic reaction and is life threatening if not immediately treated.

Prevalence levels for allergic disease are collated from a range of National Health Surveys, Census data and hospital admissions. However, there is no nationwide data collection to provide accurate statistics on allergic disease to assist future research. To understand allergies better, this report recommends the establishment of a national centre for allergies and anaphylaxis to undertake research on current and emerging allergies and to establish a national register for anaphylaxis and drug allergies.

Australia is currently a world leader in allergy research, but further research is necessary to understand and treat allergic disease. For example, vital work on the treatment of insect allergy has happened in Australia, including the breakthrough development of Jack Jumper Ant venom immunotherapy in Tasmania, as well as work on tick allergies. While there has been progress in understanding food allergy, with hospital admissions for food allergy increasing four fold over the past 10 years, it is crucial that further research be undertaken to assist with prevention, diagnosis, treatment and ultimately a cure. The Committee's recommendation to establish a national centre for allergies and anaphylaxis will facilitate long term research into allergies.

Australia has a ten per cent rate of food allergies for infants up to 12 months. This makes infant feeding particularly stressful for many Australian parents and long term it can have an overall negative impact on the quality of life for the individual and the family. The Committee received evidence from many parents who vigilantly manage their child's severe and sometimes life-threatening food allergies. Daily life, including activities such as attending school or work and social engagements, is stressful for many people living with allergies. In some severe cases, it is extremely debilitating. Food is not only vital for life; it plays a large part in our social lives. Many people – both children and adults – told the Committee how their food allergies left them feeling excluded from social occasions.

For many people with food allergies, food labels cause daily challenges. The Committee heard that improvements to Plain English Allergen Labelling are currently underway that will make allergen labelling clearer and more consistent. The Committee recommends that these improvements be expedited to assist people living with food allergies.

Precautionary Allergen Labelling is an issue that causes frustration and anxiety for people with food allergy. This type of labelling informs food consumers of the possible presence of food allergens in a product when the allergen was not intentionally added but may have occurred due to cross contact. Most people would have read on the back of a food package words like “may contain tree nuts”. Up to sixty-five per cent of processed foods have a precautionary allergen label. This report recommends the development of a label to demonstrate that a food product has been assessed for certain allergens. This will lead to improved consumer confidence for some food products and will reduce the risks for people with food allergies every time they consume packaged food items.

As there is no cure for allergies, the current expert advice is to avoid the allergen if it is known. In the event of an anaphylactic reaction, an adrenaline auto-injector or EpiPen is required to treat patients and hospital admission is required. It was concerning to hear that Australia experiences shortages of EpiPens when a manufacturing fault or contamination occurs within the production line. Currently, there is no alternative adrenaline auto-injector available in Australia. This report recommends that the Australian Government respond to this problem to encourage an alternative supplier in order to keep Australians living with allergies safe.

Many individuals, especially parents of children living with food-related allergies, advocated for the increased availability of food immunotherapy. Currently food immunotherapy is not offered in Australia and several families told the Committee they had travelled overseas to receive immunotherapy for their children. This is an

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area that will benefit from further research in Australia and this report recommends that clinical research be undertaken with the aim of being able to offer safe and well understood food immunotherapy in the future.

Data on drug allergy is needed to improve the way Australia understands allergies. Drug and medicine allergy is a complex and costly problem. Besides the risk of anaphylaxis, other adverse drug reactions may cause significant morbidity and mortality. Australia currently has no systematic collection of data about adverse drug reactions. The Committee's recommendation to establish a national centre for allergies and anaphylaxis will be important for managing a national register for drug allergy.

Australia lacks a consistent approach to allergy and anaphylaxis management. Many people reported difficulties in accessing and receiving a diagnosis, often having to see several doctors and specialists before their or their child's symptoms could be diagnosed. Timely access to specialists is a concern that was brought to the Committee's attention. Australia has a limited number of allergists and immunologists and waiting lists for both public and private specialists are between six months and two years across many parts of Australia. Most of these specialists are in or near major cities so patients in rural and regional areas must travel long distances to see allergy specialists. The Committee has recommended providing telehealth funding support for doctors and allied allergy health workers to support allergy patients in rural, regional and remote Australia.

The Committee heard there is a lot of misinformation available on the internet and this lack of consistent advice combined with long waiting times to see specialists results in people getting desperate for solutions and treatments to allergies. This report recommends a national framework be developed for allergies and anaphylaxis including a Shared Care Model for allergies and the development of Clinical Care Standards for anaphylaxis. Medical experts informed the Committee that medical education in relation to allergies and anaphylaxis was inadequate in Australia. This was the case for many General Practitioners, Paediatricians and other medical and health professionals. The incidence of drug-related anaphylaxis is high in Australia and accounts for fifty per cent of anaphylactic deaths. This is an area of concern that gets little attention despite significant health issues that arise from drug allergy mismanagement. This report highlights the need to improve education and training in allergies and anaphylaxis for all medical and health practitioners.

In addition to the medical and health profession, the Committee recognises that a majority of the population lacks a good understanding of allergies and anaphylaxis. I hope that this report assists in educating the general community and

other important industries such as food service, schools, hospitals and airline industries on allergies and anaphylaxis.

Finally, I would like to thank the individuals and organisations who took the time to write submissions and appear at public hearings. I am grateful to the people who live with allergies who shared their unique circumstances and experiences. I particularly want to thank those who discussed their traumatic experiences of losing loved ones to anaphylaxis. I hope that the recommendations in this report will lead to changes that assist people living with allergic disease to have a better quality of life in the future.

My sincere thanks to all Committee members for their engagement with this inquiry. I am especially grateful to several Committee members who contributed their own medical expertise and knowledge of this topic, which assisted the Committee to be well informed and to understand the more technical issues of the inquiry.

I also extend the Committee's thanks to the secretariat who brought their professionalism and dedication to the conduct of the inquiry.

**Mr Trent Zimmerman MP**

**Chair**

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Bass, TAS

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# Committee Secretariat

Dr Joel Bateman, Committee Secretary

Ms Rebecca Gordon, Inquiry Secretary

Ms Tegan Scott, Senior Research Officer

Ms Tamara Palmer, Office Manager



# Abbreviations

A&AA	Allergies and Anaphylaxis Australia
ACN	Australian College of Nursing
ACNP	Australian College of Nurse Practitioners
AEFI	Adverse Events Following Immunisation
AFGC	Australian Food and Grocery Council
ANZAAG	Australian New Zealand Anaesthetic Allergy Group
API	Active Pharmaceutical Ingredients
APS	Australian Paediatric Society
ARTG	Australian Register of Therapeutic Goods
ASCIA	Australasian Society of Clinical Immunology and Allergy
BTF	Biomedical Translation Fund
CFAR	Centre for Food Allergy Research
DAWE	Department of Agriculture, Water and the Environment
DoH	Department of Health
EGID	Eosinophilic Gastrointestinal Disorder
EoE	Eosinophilic oesophagitis
FCDB	Food and Controlled Drugs Branch
FPIES	Food Protein-Induced Enterocolitis Syndrome
FSANZ	Food Standards Australia New Zealand
GPs	General Practitioners

IgE	Immunoglobulin E
JJAP	Jack Jumper Allergy Program
MBS	Medical Benefits Scheme
MCRI	Murdoch Children's Research Institute
MMA	Mammalian Meat Allergy
MRFF	Medical Research Future Fund
NAS	National Allergy Strategy
NHMRC	National Health and Medical Research Council
NSW AEP	New South Wales Anaphylaxis Education Program
OFC	Oral Food Challenge
OIT	Oral Immunotherapy
PAL	Precautionary Allergen Labelling
PBS	Pharmaceutical Benefits Scheme
PEAL	Plain English Allergen Labelling
PSA	Pharmacy Society of Australia
QUT	Queensland University of Technology
SLIT	Sublingual Immunotherapy
TGA	Therapeutic Goods Administration
TiARA	Tick Induced Allergies Research and Awareness
VIT	Venom Immunotherapy
VITAL	Voluntary Incidental Trace Allergen Labelling

# List of Recommendations

## **Recommendation 1**

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2.130 The Committee recommends that the Australian Government work with the states and territories to establish a National Centre for Allergies and Anaphylaxis in Australia, to ensure there is a national standardised approach to allergy management.

## **Recommendation 2**

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2.131 The Committee recommends that the Australian Government dedicate additional funding into food allergies and anaphylaxis research, in particular funding for:

- the Centre for Food and Allergy Research (CFAR) so it can continue its work past 2022 (if Recommendation 1 has not been implemented by expanding CFAR to become a National Centre for Allergies and Anaphylaxis);
- clinical research into food allergy treatments (including allergies outside of peanut allergy) in particular into food based oral immunotherapy, including head-to-head trials (trials with no placebo);
- research into emerging allergic diseases such as eosinophilic oesophagitis and food protein-induced enterocolitis syndrome (FPIES);
- research into the social and psychological effects of allergies and anaphylaxis; and
- establishing a national register for anaphylactic episodes and death.

### **Recommendation 3**

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2.132 The Committee recommends that the Australian Government consider providing a healthcare card to people with severe and chronic allergic conditions and a carers allowance for their carers where appropriate.

### **Recommendation 4**

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3.133 The Committee recommends that the Australian Government work with all states and territories to provide a consistent national framework for patients being discharged from an Emergency Department after an anaphylactic reaction. These patients should be provided with the following:

- an adrenaline auto-injector script for up to a maximum of 3 adrenaline auto-injectors and an appropriate emergency action plan (including digitised action plans) as per the Australasian Society of Clinical Immunology and Allergy (ASCIA)'s recommendation;
- if not already diagnosed with anaphylaxis, the patient should be given a priority referral (this referral must be for the period four to six weeks after discharge) to an immunologist or allergy specialist; and
- information pamphlets on allergies and anaphylaxis. For example, information that outlines support and information on allergies from peak bodies such as ASCIA and Allergies and Anaphylaxis Australia (A&AA).

### **Recommendation 5**

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3.134 The Committee recommends that the Australasian Society of Clinical Immunology and Allergy (ASCIA) receive ongoing long term funding to continue its partnership work with the Department of Health and the National Allergy Strategy, to develop minimum standards of allergy training for health professionals including:

- funding for the promotion of the e-resources ASCIA has already developed to all relevant communities throughout Australia;
- minimum standards of allergy training in the curriculum for all university medical schools and training of general practitioners,

physicians and paediatricians, nurse practitioners, psychologists, dietitians, and paramedics; and

- funding support for ASCIA to provide training for all health professionals listed above.

## **Recommendation 6**

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3.135 The Committee recommends that the Australian Government provide telehealth funding support for doctors and allied health workers in order to provide professional services and support to allergy patients in rural, regional and remote Australia.

## **Recommendation 7**

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3.136 The Committee recommends that the Australian Government consider an Medical Benefits Scheme (MBS) item number for food challenges carried out by appropriate clinicians.

## **Recommendation 8**

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3.137 The Committee recommends that the Australian Government provides funding for a public health system drug de-labelling program including:

- developing a program in the public health system to run community education campaigns to encourage people to participate in drug allergy de-labelling programs;
- create clinical guidelines for drug allergy de-labelling; and
- give consideration to the need for a Medicare Benefits Scheme (MBS) item number for drug allergy testing and drug allergy challenges.

## **Recommendation 9**

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3.138 The Committee recommends that the Australian Government should mandate consistent labelling for all products containing chlorhexidine, iodine and latex to ensure consumers and healthcare workers can readily identify these products. In addition:

- alternatives for chlorhexidine, iodine and latex should be readily available;

- all government procurement should maintain a database of all chlorhexidine, iodine and latex containing products;
- the broader healthcare sector should be educated about the risks of anaphylaxis to chlorhexidine, iodine and latex.

### **Recommendation 10**

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3.139 The Committee recommends that the Australian Government provide additional funding support to ensure the Royal Hobart Hospital can provide ongoing Jack Jumper Ant venom immunotherapy treatment to Australians in all states and territories.

### **Recommendation 11**

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3.140 The Committee recommends that the Australian Government work with states and territories to ensure that all allergy and anaphylaxis fatalities receive an automatic referral to the coroner for assessment.

### **Recommendation 12**

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3.141 The Committee recommends that the Australian Government work with the Therapeutic Goods Administration (TGA) to:

- proactively encourage competition for pharmaceutical companies to supply alternative adrenaline auto-injectors to the Australian market in order to prevent future shortages;
- investigate the expiry dates of adrenaline auto-injectors; and
- investigate reasons for intermittent supply of adrenaline auto-injectors.

### **Recommendation 13**

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3.142 The Committee recommends that the Australian Government work with states and territories to:

- review the sufficiency of the current allergist and immunologist workforce in hospitals throughout Australia; and
- ensure that there is funding for increased placements of these specialists in all hospitals (if a need is found).

## **Recommendation 14**

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- 4.130 The Committee recommends that the Australian Government review all work, health and safety standards within vocational education training to ensure all food service and food preparation training modules include training on allergies and anaphylaxis, including the prevention of food cross contact.

## **Recommendation 15**

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- 4.131 The Committee recommends that the Allergen Bureau in collaboration with Food Standards Australia New Zealand (FSANZ), work with the food industry to encourage the consistent use of the VITAL food allergen risk assessment program, including the introduction of a VITAL 'V' tick on packaging to inform consumers that a product has been through this process.

## **Recommendation 16**

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- 4.132 The Committee recommends that the Australian Government work with state and territories to mandate allergen regulations for all hospitals, to ensure that allergen free meals are made available to all patients.

## **Recommendation 17**

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- 4.133 The Committee recommends that Food Standards Australia New Zealand (FSANZ) expedites the finalisation of the Plain English Allergy Labelling (PEAL) process before September 2020 and informs the Committee once the process has been finalised.

## **Recommendation 18**

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- 4.134 The Committee recommends that Food Standards Australia New Zealand (FSANZ) prioritises work in relation to reformulation labels on products. Any product that has changed its ingredients should have either new packaging alerting consumers to the reformulation, or should have a sticker placed on the front stating clearly that new ingredients have been added.

## **Recommendation 19**

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4.135 The Committee recommends that all staff at Australian primary and secondary schools receive nationally consistent education and training for recognising and responding to anaphylaxis.

## **Recommendation 20**

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4.136 The Committee recommends that the Department of Health work with the Australasian Society of Clinical Immunology and Allergy (ASCIA) and all states and territories to ensure that treatment for anaphylaxis be incorporated into a nationally standardised first aid training course, and if necessary to provide additional funding to first aid training providers to facilitate this.

## **Recommendation 21**

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4.137 The Committee recommends that the Australian Government work with the Australasian Society of Clinical Immunology and Allergy (ASCIA) and state and territories to include information about allergies and anaphylaxis education and training into undergraduate teacher training degrees, learning support assistant training and childcare worker vocational education training.

## **Recommendation 22**

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4.138 The Committee recommends that the Australian Government requires that all airlines in and out of Australia undertake the following to assist with customers requiring anaphylaxis care:

- seats of travellers who have emergency care plans for anaphylaxis should be wiped down before boarding;
- cabin crew should receive first aid training that includes anaphylaxis training, recognising symptoms of anaphylaxis and an understanding of how to administer an adrenaline auto-injector; and
- require all first aid kits on domestic and international flights entering and departing Australia to carry at least two adrenaline auto-injectors.

**Recommendation 23**

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5.186 The Committee recommends that the Australian Government give consideration of how best to increase the utilisation of nurses and allied health care workers to support the care of patients with allergic disease.

**Recommendation 24**

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5.187 The Committee recommends that the Therapeutic Goods Administration and any other relevant authorities, such as the Australian Competition and Consumer Commission (ACCC) conduct an independent, evidence-based review into all therapeutic goods, services, or devices which claim to diagnose or treat allergies.



# 1. Introduction

## Background

- 1.1 Allergic disease is on the rise and creating a social and economic burden on Australian society. It is estimated that around one third of people will develop allergies in their lifetime. In Australia, food allergy affects 10 per cent of children and two per cent of adults.<sup>1</sup> Over four million Australians live with allergies or allergic diseases and this number is rising.<sup>2</sup>
- 1.2 An allergy is a person's immune system reacting to substances in the environment which are harmless for others. Substances which cause allergic reactions are known as allergens.<sup>3</sup> Atopy is a genetic tendency to develop allergic diseases. When people with atopy are exposed to allergens they develop allergic inflammation which results in conditions such as hay fever (allergic rhinitis), eczema (atopic dermatitis), hives (urticaria) or allergic asthma.<sup>4</sup>
- 1.3 Allergic disease includes several different conditions, the most common of which are food and drug allergy, atopic dermatitis, allergic rhinitis, allergic asthma, insect bite or sting allergies and latex allergy. Less common allergic conditions include idiopathic anaphylaxis (anaphylactic reactions with no

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<sup>1</sup> Allergies and Anaphylaxis Australia (A&AA), 'Allergy & Anaphylaxis' <[allergyfacts.org.au/allergy-anaphylaxis](http://allergyfacts.org.au/allergy-anaphylaxis)> viewed 24 February 2020.

<sup>2</sup> Allergies and Anaphylaxis Australia (A&AA), *Submission 184*, p. 6.

<sup>3</sup> A&AA, 'What is allergy?' <[allergyfacts.org.au/allergy-anaphylaxis/what-is-allergy](http://allergyfacts.org.au/allergy-anaphylaxis/what-is-allergy)> viewed 24 February 2020.

<sup>4</sup> Australasian Society of Clinical Immunology and Allergy (ASCIA), 'What is Allergy?' <[allergy.org.au/patients/about-allergy/what-is-allergy](http://allergy.org.au/patients/about-allergy/what-is-allergy)> viewed 24 February 2020.

known cause), eosinophilic oesophagitis (EoE) and food protein-induced enterocolitis syndrome (FPIES).<sup>5</sup>

- 1.4 In its most severe form, an allergic reaction can result in anaphylaxis which can be life threatening. Anaphylaxis is a generalised allergic reaction which can often involve more than one body system, such as the skin, respiratory, cardiovascular or gastro-intestinal systems. Common triggers for anaphylaxis are food, insect bites or stings, and medications. Less common anaphylactic triggers are latex or exercise.<sup>6</sup>
- 1.5 Between 1997 and 2013, the Australian Bureau of Statistics recorded 324 deaths from anaphylaxis.<sup>7</sup> However many allergy specialists believe this figure is underestimated due to a lack of understanding of anaphylaxis within the medical profession.

## About the inquiry

### Objectives and scope

- 1.6 On 27 August 2019, the Minister for Health, the Hon Greg Hunt MP, referred the *Inquiry into Allergies and Anaphylaxis* (the inquiry) to the Standing Committee on Health, Aged Care and Sport (the Committee).
- 1.7 As part of the inquiry the Committee reviewed the prevalence and treatment of allergies and anaphylaxis in Australia. More specifically the Committee examined:
  - an overview of allergies and anaphylaxis, including food and drug allergy, as well as other allergic diseases such as eczema, allergic rhinitis and others;
  - the management and treatment of allergies and anaphylaxis, including topics such as food labelling and food service, access to adrenaline auto-injectors and access to medical services for allergy and anaphylaxis sufferers; and
  - research into possible causes of allergy and emerging treatments and therapies, including research into food based oral immunotherapy.

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<sup>5</sup> Allergies and Anaphylaxis Australia (A&AA), *Submission 184*, p. 6.

<sup>6</sup> A&AA, 'What is Anaphylaxis?' <[allergyfacts.org.au/allergy-anaphylaxis/what-is-anaphylaxis](http://allergyfacts.org.au/allergy-anaphylaxis/what-is-anaphylaxis)> viewed 24 February 2020.

<sup>7</sup> National Allergy Strategy, *Submission 118*, p. 10.

1.8 The Committee received a number of personal accounts from people who suffer from allergies as well as the parents of children suffering from allergies and anaphylaxis. Members of the Committee appreciate the effort taken by these people to participate in the inquiry. The personal accounts provided the Committee with valuable insights into the impacts of allergies and anaphylaxis.

## **Inquiry conduct**

1.9 On 12 September 2019, the Committee issued a media release announcing the inquiry and calling for submissions. The Committee invited submissions from government agencies, peak industry and professional organisations, community support and patient advocacy groups, health providers specialising in allergy care, research organisations and universities, and the general public.

1.10 The inquiry received 257 submissions and five exhibits, which are listed at Appendix A and B respectively.

1.11 The Committee held seven public hearings as outlined in the table below. A list of witnesses and organisations who attended these public hearings is in Appendix C.

**Table 1.1 Public hearings held**

<b>Date</b>	<b>Place</b>
24 October 2019	Canberra, ACT
6 February 2020	
13 February 2020	
18 November 2019	Melbourne, VIC
19 November 2019	Sydney, NSW
17 February 2020	Adelaide, SA
18 February 2020	Brisbane, QLD

## **Report structure**

1.12 Chapter 2 provides an overview of allergies and anaphylaxis in Australia. This includes definitions and prevalence levels of various allergies, the impacts and costs of allergies and anaphylaxis, theories on possible causes,

and a discussion on the availability of allergy and anaphylaxis data in Australia.

- 1.13 Chapter 3 discusses the support and management currently available for people suffering from allergies and anaphylaxis in Australia. This includes government partnerships, access to treatment, including long waiting lists to see specialists and limited access to specialists in rural and remote Australia. Drug allergy management including drug de-labelling is discussed as well as sting allergy management.
- 1.14 Chapter 4 reviews the issues raised in relation to food labelling. It discusses the Food Standards Australia New Zealand Code that regulates requirements for all food labelling in Australia as well as Plain English Allergen Labelling (PEAL) and Precautionary Allergen Labelling (PAL). Education and training needs for allergies and anaphylaxis are discussed for various sectors including the medical sector as well as allergen management in the food service industry.
- 1.15 Chapter 5 outlines research funding for allergies and current clinical trials for food allergies that are available in Australia. It discusses food based oral immunotherapy (OIT) which is not yet available in Australia but is available in some overseas countries. This chapter discusses new treatments for severe eczema and alternative medicines and therapies being used for allergy treatments in Australia.

## 2. Overview of allergies and anaphylaxis in Australia

### Overview

- 2.1 Allergic disease currently affects more than four million Australians and is rising in prevalence.<sup>1</sup> It negatively impacts on individuals' and families' quality of life, especially for those people with multiple or severe allergic diseases. Living with allergies, and in particular the risk of anaphylaxis, can create high levels of anxiety for individuals and their families in everyday life.
- 2.2 It is estimated that allergies and anaphylaxis have been on the rise in Australia over several decades. As there is no cure this has become a significant public health issue. Many Australians have more than one allergic disease state and many families have several family members living with allergic disease. Research suggests that 'a parental history of both parents having allergic disease equates to offspring having a 60 per cent chance of developing allergic disease.'<sup>2</sup>
- 2.3 Australia is often referred to as the 'allergy capital of the world'. However, Australia's allergy rates are probably not dissimilar to other developed countries such as the United Kingdom (UK) and the United States of America (USA).<sup>3</sup>

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<sup>1</sup> Allergies and Anaphylaxis Australia (A&AA), *Submission 184*, p. 6.

<sup>2</sup> A&AA, *Submission 184*, p. 6.

<sup>3</sup> Dr Joanne Smart, Director, Department of Allergy and Immunology, Royal Children's Hospital, Melbourne, *Committee Hansard*, 18 November 2019, p. 18.

- 2.4 The term allergic disease covers several disease states, including but not limited to, atopic dermatitis (eczema), allergic rhinitis (hay fever), allergic asthma, food allergy (including mammalian meat allergy), drug allergy, latex allergy, insect allergy (including tick allergy), exercise induced anaphylaxis (often food dependant), idiopathic anaphylaxis (no known cause) and cold urticaria (hives).<sup>4</sup>
- 2.5 This chapter addresses the prevalence rates of allergies and anaphylaxis in Australia, diagnostic methods, costs of living with allergies and theories of possible causes on this significant health issue affecting many Australians.

## Definition of allergy

- 2.6 Allergy occurs when a person reacts to substances in the environment that are harmless to most people. These substances are known as allergens and are found in dust mites, pets, pollen, insects, ticks, moulds, foods and some medications.
- 2.7 Food allergies can be divided into two types: IgE mediated and non IgE mediated. Immunoglobulin E (IgE) are antibodies produced by the immune system. If you have an allergy, your immune system overreacts to an allergen by producing antibodies called IgE. These antibodies travel to cells that release chemicals, causing an allergic reaction. A blood test can ascertain levels of IgE that can be used to confirm allergies.<sup>5</sup>
- 2.8 The signs and symptoms of IgE mediated food allergy usually occur within minutes of ingestion and includes hives, redness of skin, vomiting and in some severe reactions anaphylaxis.<sup>6</sup>
- 2.9 Non IgE mediated food allergies are caused by a reaction involving other components of the immune system apart from IgE antibodies.<sup>7</sup> Endoscopies, colonoscopies and biopsies are required to diagnose non IgE mediated allergies.<sup>8</sup>

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<sup>4</sup> A&AA, *Submission 184*, p. 6.

<sup>5</sup> American Academy of Allergy Asthma and Immunology, < [https://www.aaaai.org/conditions-and-treatments/conditions-dictionary/immunoglobulin-e-\(ige\)](https://www.aaaai.org/conditions-and-treatments/conditions-dictionary/immunoglobulin-e-(ige))> accessed 25 March 2020.

<sup>6</sup> American Academy of Allergy Asthma and Immunology, < [https://www.aaaai.org/conditions-and-treatments/conditions-dictionary/immunoglobulin-e-\(ige\)](https://www.aaaai.org/conditions-and-treatments/conditions-dictionary/immunoglobulin-e-(ige))> accessed 25 March 2020.

<sup>7</sup> The Royal Children's Hospital Melbourne, Allergy and Immunology, <

<sup>8</sup> Professor Brendan Murphy, Chief Medical Officer, Department of Health, p. 5.

- 2.10 Atopy is the genetic tendency to develop allergic diseases. When atopic people are exposed to allergens they can develop an immune reaction that leads to allergic inflammation. This can cause symptoms in the:
- Nose and/or eyes, resulting in allergic rhinitis (hay fever) and/or conjunctivitis;
  - Skin, resulting in eczema, or hives (urticaria); and
  - Lungs, resulting in asthma.<sup>9</sup>
- 2.11 When a person who is allergic to a particular allergen comes into contact with it, an allergic reaction occurs:
- When the allergen (such as pollen) enters the body, it triggers an antibody response;
  - The antibodies attach themselves to mast cells;
  - When the pollen comes into contact with the antibodies, the mast cells respond by releasing histamine; and
  - When the release of histamine is due to an allergen, the resulting inflammation (redness and swelling) is irritating and uncomfortable.<sup>10</sup>
- 2.12 Similar reactions can occur to some chemicals and food additives. However if they do not involve the immune system, they are known as adverse reactions, not allergy.<sup>11</sup>

## Anaphylaxis

- 2.13 Anaphylaxis is the most severe form of allergic reaction and is life threatening if not immediately treated. Anaphylaxis is an allergic reaction involving more than one body system, for example: skin, respiratory, gastrointestinal and/or cardiovascular.<sup>12</sup>
- 2.14 The most common triggers of anaphylaxis are foods, insect stings and drugs or medications. Anaphylaxis is indicated by any one of the following signs:

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<sup>9</sup> ASCIA website, The definition of allergy, < <https://www.allergy.org.au/patients/about-allergy/what-is-allergy>> accessed 21 February 2020.

<sup>10</sup> ASCIA website, The definition of allergy, < <https://www.allergy.org.au/patients/about-allergy/what-is-allergy>> accessed 21 February 2020.

<sup>11</sup> ASCIA website, The definition of allergy, < <https://www.allergy.org.au/patients/about-allergy/Life-threatening-allergic-reactions-require-immediate-treatment>> accessed 21 February 2020.

<sup>12</sup> Department of Health (DoH) website, Reporting and Managing adverse vaccination events, < <https://www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events#what-is-an-adverse-event-following-immunisation-aei>> accessed 30 January 2020.

- Difficult/noisy breathing;
  - Swelling of the tongue;
  - Swelling/tightness in throat;
  - Difficult talking and/or hoarse voice;
  - Wheeze or sudden persistent cough;
  - Persistent dizziness or collapse;
  - Pale and floppy (young children); and
  - Abdominal pain, vomiting (for insect sting or injected drug allergy).<sup>13</sup>
- 2.15 Adrenaline (epinephrine) is the first line treatment of anaphylaxis and acts to reduce airway mucosal oedema, induce bronchodilation, induce vasoconstriction and increase strength of cardiac contraction. The dosage of adrenaline depends on the weight of the person. Currently there are two doses of adrenaline auto-injectors available in Australia:
- EpiPen (0.3 mg) is usually prescribed for adults and children over 20kg; and
  - EpiPen Junior (0.15mg) is usually prescribed for children 7.5kg – 20kg. Children under 7.5kg are not usually prescribed an adrenaline auto-injector device.<sup>14</sup>
- 2.16 Not all individuals with food allergy will experience anaphylaxis. However understanding risk factors for anaphylaxis among those with food allergy is critical to inform prevention and management strategies.<sup>15</sup>
- 2.17 Australia lacks a structured reporting system to capture data on the incidence of anaphylaxis, therefore the true incidence of anaphylaxis is unknown. An anaphylaxis notification scheme was recently established in Victoria but is only available in that state. Available data indicates that deaths from anaphylaxis have increased.<sup>16</sup>
- 2.18 The Australasian Society of Clinical Immunology and Allergy (ASCIA) is the peak professional body for allergy and clinical immunology in Australia and New Zealand. ASCIA stated that one in five (20 per cent) Australians are

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<sup>13</sup> ASCIA, Signs and symptoms of allergic reactions, website <  
<https://www.allergy.org.au/hp/papers/acute-management-of-anaphylaxis-guidelines>> accessed 24 February 2020.

<sup>14</sup> ASCIA website, adrenaline auto-injector dose recommendations, <  
<https://www.allergy.org.au/hp/anaphylaxis/adrenaline-autoinjector-prescription>> accessed 24 February 2020.

<sup>15</sup> Centre for Food and Allergy Research (CFAR), *Submission 97*, p. 2.

<sup>16</sup> National Allergy Strategy (NAS), *Submission 118*, p. 5.

affected by allergies and anaphylaxis.<sup>17</sup> This figure includes allergies to food, drugs, insect venom, ticks, environmental allergens such as pollen and grasses, latex and chemical products used in cleaning and cosmetics.

2.19 Dr Mullins, allergist and immunologist, recently reviewed all cases of fatal anaphylaxis referred to the coroner in the last 20 years in Australia. The findings showed 'Unlike the UK and the USA, anaphylaxis fatalities have increased in Australia in parallel with increasing hospital anaphylaxis admission rates.'<sup>18</sup>

2.20 The following figures provided by Dr Mullins demonstrate the increasing hospital admission rates in Australia:

In our most recent publication examining increasing rates of Australian anaphylaxis admission rates, we described food and total anaphylaxis admission rates in children aged 0-4 year to be 7.3 and 9 per 100,000 population in 1999, rising to 30.2 and 34.8 per 100,000 population for the financial year ending June 2012. Our most recent (unpublished) analysis for the year ending June 2018 shows even higher rates of 46 and 53.2 per 100,000 population, respectively.<sup>19</sup>

2.21 The Centre for Food and Allergy Research (CFAR) provides a network for collaboration amongst paediatric food allergy researchers, clinicians and communities affected by food allergy.

2.22 CFAR researchers have shown that:

Australia has the highest prevalence of IgE-mediated food allergy in the world, with a staggering 10 per cent of infants with challenge-proven food allergies, and of greatest concern, an increasing associated fatality rate. Rates of anaphylaxis have continued to rise over the period 2005-2015, with a second rise in the adolescent age group, and a five-fold increase in hospital admissions for anaphylaxis between 1995 and 2005.<sup>20</sup>

2.23 CFAR noted that 'Hospital admissions data from 1998-2012 showed that food-induced anaphylaxis was the most common cause of hospital admissions for anaphylaxis in Australia. Hospital admissions for food-

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<sup>17</sup> ASCIA, *Submission 153*, p. 1.

<sup>18</sup> Dr Ray Mullins, Immunologist, *Submission 205*, p. 4.

<sup>19</sup> Dr Mullins, *Submission 205*, p. 3.

<sup>20</sup> CFAR, *Submission 97*, p. 2.

induced anaphylaxis were highest in young children (under 5 years of age).<sup>21</sup>

- 2.24 CFAR also found that ‘adolescents with nut allergy were at increased risk of anaphylaxis compared with those with other food allergies.’<sup>22</sup>
- 2.25 Most drug-related anaphylaxis fatalities occur in a medical setting, which triggers an automatic referral to the coroner for assessment. This allows for lessons to be learned regarding the most common triggers, to facilitate the accuracy of medical records and processes to be identified that might reduce the risk of further inadvertent exposure.<sup>23</sup>
- 2.26 Dr Mullins commented that ‘it is highly likely that food related anaphylaxis is underreported or may not even be suspected if it occurs at home away from a hospital or is unwitnessed.’ Dr Mullins emphasised that ‘death may not necessarily be attributed to anaphylaxis as there are no autopsy specific features of anaphylaxis.’<sup>24</sup>
- 2.27 CFAR highlighted the issue of mismanagement of anaphylactic patients:
- Across Australia, anaphylaxis continues to be mismanaged with many people treated sub-optimally – including not being given adrenaline (epinephrine) which is the first line treatment for anaphylaxis. Patients are discharged without a prescription for an adrenaline auto-injector (EpiPen) or a referral to see a clinical immunology/allergy specialist for follow up care.<sup>25</sup>

## Prevalence of allergic disease

- 2.28 Australian medical professionals agree that allergies and rates of anaphylaxis are increasing; however precise statistics are not available. Prevalence levels for allergic disease are generally collated from a range of National Health Surveys, Census data and hospital admissions data. Prevalence rates of allergic disease are highest in young children but are also increasing in adolescents and young adults.
- 2.29 The figures below break down the prevalence levels for some allergic disease in Australia:

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<sup>21</sup> CFAR, *Submission 97*, p. 2.

<sup>22</sup> CFAR, *Submission 97*, p. 6.

<sup>23</sup> Dr Mullins, *Submission 205*, p. 4.

<sup>24</sup> Dr Mullins, *Submission 205*, p. 4.

<sup>25</sup> NAS, *Submission 118*,

- around 10% of infants in Australia are affected by food allergy by the time they are 12 months old;
- 1 in 9 Australians have asthma and of these 3-10% have severe asthma;
- 1 in 5 Australians have allergic rhinitis;
- around 25% of the population will suffer from urticaria (hives) at some point in their lives and up to 3% will have chronic urticaria;
- anaphylaxis is reported to occur on 0.2% of children and 3% of adults, but an increase in incidence has been reported over time; and
- around 32% of Australia's population will have atopic dermatitis at some point in their life.<sup>26</sup>

2.30 The increase in allergies in Australia over recent decades has resulted in long waiting lists to see specialists and has put a strain on medical services including allergists, immunologists and allergy nurses in the public and private systems. Access to expert advice and treatment will be discussed further in chapter 3.

### *Food allergy*

2.31 Food allergy rates are highest for infants. However, while some infants grow out of allergies, some people develop allergies in adulthood. ASCIA reports that 'food allergy occurs in around 10% of infants, 4-8% of children, and about 2% of adults in Australia and New Zealand.'<sup>27</sup>

2.32 Research shows that while some children outgrow their allergies to cow's milk, soy, wheat or egg, approximately 75% of children will have persistent allergies to peanut, tree nuts, sesame and seafood.<sup>28</sup>

2.33 CFAR called for additional research into factors that predict the risk of anaphylaxis among individuals with food allergy. In order to facilitate further research, the collection of anaphylaxis data is essential:

Data from a National Anaphylaxis Surveillance Unit will be required to achieve this – we envisage a model similar to the Adverse Events Following Immunisation (AEFI-CAN) reporting system.<sup>29</sup>

2.34 Dr Mullins commented on the prevalence levels of food allergy increasing over time in the absence of a cure:

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<sup>26</sup> Sanofi, *Submission 204*, p. 6.

<sup>27</sup> Department of Health (DoH), *Submission 78*, p. 5.

<sup>28</sup> DoH, *Submission 78*, p. 6.

<sup>29</sup> CFAR, *Submission 97*, p. 2.

The incidence of food allergy (or new cases occurring over a set period of time) is most common in early childhood but as children age, if allergy does not resolve spontaneously, the population prevalence (the proportion of the population currently with disease) will inevitably increase with time.

We are already observing this in Australia in older teenagers and adults who are allergic to triggers such as peanut, nuts, seeds or seafood where allergy rarely resolves, resulting in accelerating rates of hospital anaphylaxis admissions.

In absence of a cure for food allergy, population prevalence will continue to increase steadily even if incidence remains stable. If incidence also increases, then the rates of increase in prevalence will likely accelerate exponentially. Thus, food allergy prevalence will only likely stabilise if an effective cure becomes available allowing the rate of disease resolution to equal the rate of new cases, and only reduce when a greater number of cases are cured than new cases emerge. As health service demand is largely determined by prevalence, it will be vital to identify effective strategies to treat established disease and prevent new cases of food allergy.<sup>30</sup>

- 2.35 A majority of submissions to the inquiry focussed on paediatric allergy; however it is important to note that children grow up to become adolescents and then adults and will continue to experience allergies. As Professor O’Hehir of the Alfred Hospital commented ‘it’s important that we consider the needs of adult patients with allergy and anaphylaxis too.’<sup>31</sup>

#### *Non IgE mediated allergy*

- 2.36 As well as rising rates of IgE mediated (rapid onset) food allergy and anaphylaxis, there is also emerging evidence that non IgE mediated (delayed inflammatory) food allergy such as allergic gastroenteritis and eosinophilic oesophagitis (EoE) is also increasing in incidence.
- 2.37 Dr Mullins commented on the rising allergic gastroenteritis admission rates in Australian hospitals:

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<sup>30</sup> Dr Mullins, *Submission 205*, p. 3.

<sup>31</sup> Professor O’Hehir, Director, Department of Allergy, Immunology and Cystic Fibrosis; Alfred Health; Head of Department, Allergy, Clinical Immunology and Respiratory Medicine, Central Clinical School, Monash University, *Committee Hansard*, Melbourne, 18 November 2019, p.12.

Our data showed an increase in so-called allergic gastroenteritis admission rates in Australian babies from 6.8 per 100,000 population in 1998 to 26.6/100,000 in 2014.<sup>32</sup>

2.38 Professor Douglass of The Royal Melbourne Hospital agreed that the rate of eosinophilic oesophagitis is increasing within the population:

...we are seeing more eosinophilic oesophagitis in the young adult men, which is an area that I think really does need some attention in terms of possible biologics and equitable treatment.<sup>33</sup>

2.39 A peak body for eosinophilic oesophagitis, ausEE, commented that 'EoE affects people of all ages, gender and ethnic backgrounds and in some families, there may be an inherited (genetic) tendency.'<sup>34</sup>

2.40 CFAR commented that non IgE mediated food allergy has received far less research attention and as a result, much less is known about how to prevent and treat these disorders:

There are a number of non IgE mediated food allergic disorders (for example, infantile proctocolitis and food induced enteropathy) that are transient and disappear in early childhood. Despite this, they can still have a significant impact on child and family quality of life at a critical stage of early life. By contrast, eosinophilic oesophagitis (EoE) is a delayed inflammatory reaction of the oesophagus affecting children through to adults where resolution is rare. Population prevalence is estimated at 1/1000 and morbidity from difficulty swallowing or choking on food and food impaction significantly impacts on quality of life. Treatment options are limited to medication or trials of dietary restriction.<sup>35</sup>

2.41 Dr Mullins estimated incidence of Food Protein Induced Enterocolitis Syndrome (FPIES) is around 1/10,000 individuals although the true incidence is likely much higher due to poor recognition and underreporting.<sup>36</sup>

## *Drug and medicine allergy*

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<sup>32</sup> Dr Mullins, *Submission 205*, p. 3.

<sup>33</sup> Professor Joanne Douglass, Head, Department of Clinical Immunology and Allergy, The Royal Melbourne Hospital, *Committee Hansard*, Melbourne, 18 November 2019, p. 18.

<sup>34</sup> ausEE, *Submission 168*, p. 2.

<sup>35</sup> CFAR, *Submission 97*, p. 9.

<sup>36</sup> Dr Mullins, *Submission 205*, p. 6.

- 2.42 Drug and medicine allergy is an important, complex and costly problem. Besides the risk of anaphylaxis, other adverse drug reactions (such as severe cutaneous adverse reactions or SCAR) may cause significant morbidity and mortality. Currently in Australia, there is no systematic way of collecting data about adverse drug reactions.<sup>37</sup>
- 2.43 The NAS commented ‘Up to 25 per cent of patients presenting to hospital report a drug allergy (commonly antibiotics), which has a major impact on antimicrobial stewardship. Many studies have shown that only 10 per cent of those claiming a drug allergy are truly allergic. The importance of a correct diagnosis of a person’s drug allergy status is vital as this allows for the use of the most appropriate medications.’<sup>38</sup>
- 2.44 Some of the statistics on allergies is self-reported from the ABS data collections. In the 2014-15 National Health Survey, 4.7 per cent of Australians reported having a drug allergy.<sup>39</sup> This issue will be discussed further in chapter 3.
- 2.45 Professor Douglass noted the high incidence of drug-related anaphylaxis death in Australia.
- ...whilst 20 or 25 per cent of deaths are likely due to food allergy, probably over 50 per cent are due to drug allergy—and that's dominantly in adults—and therefore the major cause of anaphylaxis death is actually drug allergy. So, if we're looking at anaphylaxis, we have to think about that as a cause and think what might be done around that.<sup>40</sup>

## *Eczema*

- 2.46 Eczema (also called atopic dermatitis) affects the skin, causing redness, itching and sometimes infections. Eczema that gets worse is called an eczema flare. Usually there is no single trigger for an eczema flare. Eczema can vary from a mild itch to a debilitating condition that has a huge impact on quality of life.
- 2.47 Eczema is a chronic health problem that affects many people of all ages, but is most common in infants:

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<sup>37</sup> NAS, *Submission 118*, p. 7.

<sup>38</sup> NAS, *Submission 118*, p. 7.

<sup>39</sup> DoH, *Submission 78*, p. 5.

<sup>40</sup> Professor Douglass, *Committee Hansard*, Melbourne, 18 November 2019, p. 15.

- infantile eczema occurs in around one in five children under two and usually improves by five years of age;
- childhood eczema may follow or starts from two to four years of age. Rashes and dryness are usually in elbow creases, behind the knees, across ankles, or on face, ears and neck; and
- adult eczema symptoms also occur in these areas and can cause rough, hard and thickened skin.<sup>41</sup>

2.48 Eczema SUPPORT Australia reported the following global statistics of eczema:

- 20% of children, with 10%-40% having it in the moderate to severe form;
- 9-15% of adolescents; and
- 2%-8% of adults, with 40%-45% having it in the moderate to severe form.<sup>42</sup>

2.49 Up to 80 per cent of children with eczema will develop asthma later in childhood. Eczema sufferers also tend to have food allergies, asthma and hay fever.<sup>43</sup>

2.50 Eczema is not exclusively a childhood disease. It can be severe, and it is a chronic, lifelong condition (where symptoms vary over time). The consensus across Europe, USA and Australia is that the prevalence and severity of eczema is on the increase.<sup>44</sup>

## *Asthma*

2.51 Asthma is a lifelong condition of the airways. About one in nine people in Australia have asthma, which is one of the highest rates in the world. While in many cases it is a manageable condition, asthma leads to the deaths of over 400 Australians each year.<sup>45</sup>

2.52 Asthma affects people of all ages and can appear at any stage of life, with symptoms including wheezing, coughing, breathlessness or shortness of breath, and chest tightness. This is due to a temporary narrowing of the

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<sup>41</sup> ASCIA website, Symptoms of eczema, < <https://www.allergy.org.au/patients/skin-allergy/eczema> > accessed 24 March 2020.

<sup>42</sup> Eczema Support Australia, *Submission 172*, p. 4.

<sup>43</sup> Eczema Support Australia, *Submission 172*, p. 2.

<sup>44</sup> Eczema Support Australia, *Submission 172*, p. 5.

<sup>45</sup> Asthma Australia, *Submission 230*, p. 2.

airways. People with asthma often experience symptoms at night, early in the morning or after physical activity.<sup>46</sup>

- 2.53 People with asthma are likely to also experience allergies or anaphylaxis throughout their lives, with the Murdoch Children’s Research Institute finding that teenagers with food allergy are four times more likely to report having asthma.<sup>47</sup>
- 2.54 ASCIA stated ‘asthma, food allergy and high risk of anaphylaxis (severe allergic reaction) frequently occur together and asthma increases the risk of fatal anaphylaxis.’<sup>48</sup>

### *Allergic rhinitis (hay fever)*

- 2.55 Allergic rhinitis is more commonly known as hay fever. It is caused by the nose and eyes coming into contact with environmental allergens such as pollens, dust mite, moulds, and animal dander. The National Health Survey suggests 4.6 million Australians (19.3 per cent of the population) are affected by allergic rhinitis.

### *Tick allergy*

- 2.56 The connection between tick allergy and anaphylaxis is a relatively new discovery and is the only allergy where the trigger (tick bite) is known. Mammalian Meat Allergy after tick bite (MMA) was first reported in 2007 in Australia by Professor van Nunen et al. MMA has been identified in 17 countries around the world.<sup>49</sup>
- 2.57 The Tick Induced Allergies Research and Awareness (TiARA) organisation informed the Committee that tick induced allergies comprise:
- tick anaphylaxis;
  - food carbohydrate induced enterocolitis syndrome (FCIES); and
  - large local reactions to ticks.<sup>50</sup>
- 2.58 The allergen in the mammalian meat has been found to be a carbohydrate molecule called galactose-alpha 1, 3-galactose (“alpha gal”). Tick

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<sup>46</sup> Asthma Australia, *Submission 230*, p. 2.

<sup>47</sup> Asthma Australia, *Submission 230*, p. 2.

<sup>48</sup> Asthma Australia, *Submission 230*, p. 2.

<sup>49</sup> Tick Induced Allergies Research and Awareness (TiARA), *Submission 137*, p. 1.

<sup>50</sup> TiARA, *Submission 137*, p. 1.

anaphylaxis, on the other hand, is due to the development of an allergy antibody to tick salivary protein.<sup>51</sup>

- 2.59 Worldwide, Australia has the highest prevalence of mammalian meat allergy and tick anaphylaxis. The prevalence rate for MMA is 113/100 000. TiARA commented that ‘modelling the effects of global warming indicates that higher tick exposure will occur in the future.’<sup>52</sup>
- 2.60 More than 50 per cent of Australians live in regions where the Australian paralysis tick is endemic and a second tick species in Western Australia has been described as a cause of MMA, increasing the exposure of the Australian population to around 60 per cent.<sup>53</sup>
- 2.61 TiARA stated that tick anaphylaxis has caused four fatalities between 1997 and 2013.<sup>54</sup>

### *Latex allergy*

- 2.62 Exposure to latex can lead to generalised and serious allergic reactions, including anaphylaxis. Latex is most often associated with disposable gloves, but other common items that may contain latex include balloons, bandages, rubber bands, paint, swimming caps, condoms and syringes.<sup>55</sup>
- 2.63 Latex allergy is a well-recognised occupational allergy and regular use of latex gloves can trigger sensitisation and allergy in up to 30 per cent of healthcare workers.<sup>56</sup>
- 2.64 Most adverse reactions to latex are irritant dermatitis, which is not an immediate allergic reaction. It results in rough, dry, scaly skin, sometimes with weeping sores. Some proteins in latex are also present in foods and some people with latex allergy find certain foods cause itchy mouth or throat swelling, such as banana, avocado, kiwi fruit, passionfruit, plums, strawberry and tomato.<sup>57</sup>

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<sup>51</sup> TiARA, *Submission 137*, p. 1.

<sup>52</sup> TiARA, *Submission 137*, p. 1.

<sup>53</sup> TiARA, *Submission 137*, p. 1.

<sup>54</sup> TiARA, *Submission 137*, p. 2.

<sup>55</sup> South Australian Department of Education, Procedure Health support planning: Anaphylaxis and severe allergies in education and care, August 2018, p. 24.

<sup>56</sup> Globalaai, *Submission 54*, p. 1.

<sup>57</sup> ASCIA website, Latex allergic people may also be sensitive to certain foods, <<https://www.allergy.org.au/patients/other-allergy/latex-allergy>> accessed 26 March 2020.

## *Insect allergy*

- 2.65 The following insect stings are known causes of anaphylaxis: bees, wasps, Jack Jumper Ants and Green Ants.<sup>58</sup> Allergies to venoms from stinging insects are one of the most common causes of severe allergic reactions (anaphylaxis) in Australia.
- 2.66 Allergy to Jack Jumper Ant<sup>59</sup> is a problem that is unique to Australia. The ants are only found in the cooler areas of south-western and south-eastern Australia. Jack Jumper Ant 'hotspots' are found in the Adelaide Hills, rural and semi-rural areas around Melbourne and widely spread throughout Tasmania. Jack Jumper Ant stings are the second most common cause of sting anaphylaxis in Southern and South-Eastern Australia.<sup>60</sup>
- 2.67 The Royal Adelaide Hospital noted that in 1149 consecutive cases presenting with anaphylaxis to Royal Hobart Hospital, Jack Jumper Ant venom was dominant amongst all potential causes of anaphylaxis, including penicillin and nut allergy:

In South Australia, a state with the highest prevalence of hospitalisation for allergy to honey bee stings in Australia, it accounts for around 30% of insect sting allergy referrals, far outnumbering the combined total for "European" wasps, paper wasps and other stinging ants. There have been at least 4 deaths in Australia due to JJA anaphylaxis prior to the introduction of JJA venom immunotherapy treatment.<sup>61</sup>

- 2.68 The Department of Industry, Innovation and Science told the Committee that new and novel foods made from insect protein have the potential to introduce new allergens to the Australian diet:

The allergens may be introduced either as new foods, or by modification of familiar foods, which become more allergenic to unsuspecting consumers. For example, insect proteins are likely to be highly allergenic to sensitive individuals. Phylogenetically, insects and crustaceans (including shellfish) are closely related and the muscle proteins that shellfish allergic individuals react to (tropomyosins) are known to be very similar to those in insects. Severe allergic reactions, including anaphylactic shock, appear to have affected

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<sup>58</sup> NAS, *Submission 118*, p. 2.

<sup>59</sup> *Myrmecia pilosulais*

<sup>60</sup> Royal Adelaide Hospital, *Submission 178*, p. 2

<sup>61</sup> Royal Adelaide Hospital, *Submission 178*, p. 2

people with a known shellfish allergy after they have ingested insect-based proteins.<sup>62</sup>

## Diagnosis

- 2.69 The terms 'allergy' and 'intolerances' are frequently misused within the community and it is important to distinguish true immune mediated allergy from intolerances.
- 2.70 Diagnostic tools include measures of sensitisation such as skin prick tests and blood tests for specific IgE mediated food allergy for some foods. However these tests only determine sensitisation and many patients still require a food challenge to confirm clinical food allergy status. Skin prick testing reagents are of variable quality and are not available for all allergens such as some tree nuts, fish and shellfish.<sup>63</sup>
- 2.71 While skin prick tests and blood tests (serum specific IgE) suggest the probability of a patient having a food allergy, they do not definitively confirm food allergy, nor are they the most reliable way to see if a patient has outgrown their food allergy.<sup>64</sup>
- 2.72 An increase in skin prick tests and blood tests for allergy screening has potentially lead to an over diagnosis of food allergy. Dr Joanne Smart, Director, Department of Allergy and Immunology, Royal Children's Hospital commented that this is problematic and requires further research as it may lead to an increased risk in the development of food allergy if certain foods are avoided in infancy:

What has happened over the last 20 years is that there has been a significant change in clinical practice that has been adopted by some practitioners faster than others. Conventional allergy testing, which is generally robust for confirmation where there has been an allergic reaction, has occurred, but when it's used indiscriminately to screen for food allergy, in particular in infants under the age of two, it can lead to over diagnosis and unnecessary dietary restriction. Evidence shows that this may even increase the risk for the development of food allergy in that infant.<sup>65</sup>

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<sup>62</sup> Department of Industry, Innovation and Science (DIIS), *Submission 253*, pp. 5-6.

<sup>63</sup> CFAR, *Submission 97*, p.8.

<sup>64</sup> Dr Dean Tey and Dr Preeti Joshi, *Submission 235*, p. 1.

<sup>65</sup> Dr Joanne Smart, Director, Department of Allergy and Immunology, The Royal Children's Hospital, Melbourne, *Committee Hansard*, Melbourne, 18 November 2019, p. 14.

2.73 Accurate identification of the individual foods to which a patient is allergic is critical for the management of food allergy and prevention of allergic reactions. The current gold standard for diagnosis of food allergy is an oral food challenge (OFC), which requires specialist medical supervision. OFCs are used to determine whether:

- a suspected food allergy is an actual allergy (where clinical history/allergy tests are unclear);
- individuals with a confirmed food allergy can safely eat alternative but related foods (such as other types of nuts); or
- a child has outgrown an existing confirmed food allergy.<sup>66</sup>

2.74 CFAR discussed the importance of the research it is undertaking in relation to food desensitisation, also called food based oral immunotherapy:

Despite excellent gains in our understanding of food allergy, there is much work to be done. We have major gaps in evidence of the efficacy, safety, cost-effectiveness and impact in the short and long term of desensitisation treatments (e.g.: oral immunotherapy). We need to better understand the various options for treatment through head-to-head trials in Australian children. In order to develop appropriate decision-making tools to allow evaluation of which treatment (if any) is most suitable for which patient, we need to better understand the prevalence, risk factors, immune mechanisms and genetics of food allergy, and to improve biomarkers for diagnosis and prognosis.<sup>67</sup>

2.75 CFAR has developed diagnostic tools for improving the accuracy of peanut and egg allergy diagnosis using allergen component resolved diagnostics (CRD). However these promising findings require further research and validation before they can be used in a clinical setting.<sup>68</sup>

2.76 Correct therapy for asthma, which can be life threatening, and other allergic diseases relies on accurate diagnosis to inform effective treatments, preferably by combining the clinical history with confirmation by detection of allergen specific IgE.<sup>69</sup>

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<sup>66</sup> CFAR, *Submission 97*, p. 8.

<sup>67</sup> CFAR, *Submission 97*, p. 1.

<sup>68</sup> CFAR, *Submission 97*, p. 8.

<sup>69</sup> Professor Robyn O'Hehir, *Committee Hansard*, Melbourne, 18 November 2019, p. 11.

2.77 Non IgE mediated food allergies such as EoE and FPIES, infantile proctocolitis and food induced enteropathy require endoscopies, colonoscopies and biopsies into order to make a diagnosis.

2.78 The NAS stated that:

Better diagnostic tools for food and drug allergies are required as this may allow doctors to distinguish between food/drug tolerant and allergic patients without the need for skin testing and potentially harmful challenges; this would be a huge cost saver and make assessment of allergies a lot safer.<sup>70</sup>

## Costs to individuals and the Australian health system

2.79 Allergies come at a significant cost to individuals with allergies, families of allergy sufferers, and the community.

2.80 Food allergies are estimated to cost the Australian economy \$7 billion each year, with the greatest contributor being lost productivity (71 per cent of total cost). In the context of anaphylaxis it is important to remember that the cost of the hospital presentation, treatment and health care follow up are only a small part of the economic impact. The impact on carers and their time is likely to be profound. There is a paucity of data on health-related quality of life associated with food allergy and anaphylaxis in children and adolescents, and their carers.<sup>71</sup>

2.81 Financial burden was a significant issue that was raised frequently by individual submitters who have allergies themselves or care for someone who does.<sup>72</sup> The costs of living with allergies can include: specialist fees, repeat appointments with General Practitioners (GPs) and specialists, creams and ointments, inhalers, skin treatments, alternative foods and dietician and counselling appointments. These costs could be exacerbated by having multiple children with allergies or having several comorbid allergic conditions.<sup>73</sup>

2.82 The NAS reinforced that allergies create a financial burden on families:

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<sup>70</sup> NAS, *Submission 118*, p. 8.

<sup>71</sup> CFAR, *Submission 97*, p. 2.

<sup>72</sup> Ms Emily Marney, *Submission 212*, p. 2; Mr Nathan Pokoney, *Submission 104*, pp. 2-3; Name withheld, *Submission 171*, p. 2; Ms Mareekta Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 2.

<sup>73</sup> Name withheld, *Submission 87*, p. 2; Name withheld, *Submission 227*, p. 4; Name withheld, *Submission 98*, p. 3.

Besides the cost of emergency medication, people with multiple food allergies need to buy special, more expensive foods and often spend disproportionate amounts of time in food preparation. Further to this, some treatment options (such as allergen immunotherapy) can have a significant positive impact on quality of life and may improve the course of disease but are expensive.<sup>74</sup>

- 2.83 A large part of these costs were associated with buying speciality food which did not contain allergens.<sup>75</sup> One submitter stated that her grocery bill exceeds her mortgage repayments largely due to having to buy speciality food and shop at health food stores.<sup>76</sup>
- 2.84 Many people reported making food and household products from scratch in order to ensure there were no allergens present in their homes.<sup>77</sup>
- 2.85 My Food Allergy Friends commented that:
- ...there is a huge cost financially to families, we travel up to four hours return to see an allergist and our medical bill, food bill and lost time from work has a huge impact on us. It would be great to see data collected on the average cost of allergies on families.<sup>78</sup>
- 2.86 One witness estimated that the cost of their allergies 'ranged from \$7000 - \$8000 annually, these were out of pocket expenses when accessing the private system to enable regular treatment and assessments.'<sup>79</sup>
- 2.87 The parents of a four year old who was diagnosed with FPIES at the age of 7 months, estimated the costs so far to treat their child would be 'in excess of \$20 000 on privately funded feeding therapy, access to allergy specialists, medical professional consultations and infant formula'.<sup>80</sup>

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<sup>74</sup> NAS, *Submission 118*, p. 5.

<sup>75</sup> Ms Jenny Murtagh, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 3; Mrs Pokoney, *Submission 135*, pp. 2-3; Mrs Elise Short, *Submission 130*, p. 1; Name withheld, *Submission 103*, p. 1; Name withheld, *Submission 48*, p. 2; Name withheld, *Submission 87*, p. 2.

<sup>76</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 2.

<sup>77</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 2; Mrs Short, *Submission 130*, p. 1; Name withheld, *Submission 103*, p. 1; Name withheld, *Submission 114*, p. 4; Name withheld, *Submission 48*, p. 2; Name withheld, *Submission 105*, p. 1.

<sup>78</sup> My Food Allergy Friends, *Submission 92*, p. 1.

<sup>79</sup> Mrs Karen Wong, private capacity, *Committee Hansard*, 19 November 2019, p. 6.

<sup>80</sup> Ms Alex Argenio, *Submission 188*, p. 4.

2.88 Food challenges in the private system are expensive, at approximately \$400 per allergen. If someone has multiple allergies then the cost of going private is prohibitively expensive for some families:

The point of my example is to highlight the deficiency in the availability of food challenges, which are really heralded as the gold standard in diagnosing food allergies. As I said, if I had chosen to access a private allergist it would have cost me over \$400 per allergen, and my child – and this is just my daughter I'm talking about – is allergic to more than 10 foods. And then I have my three-year-old, who is also allergic to multiple foods.<sup>81</sup>

2.89 Dr Mullins raised the issue of the high cost for FPIES:

Cost of care can at times be substantial with the need for use of expensive hypoallergenic infant formula (subsidised by Medicare) for one or two years, the need for medical review and at times, hospital challenge to prove resolution if symptoms have been severe.<sup>82</sup>

2.90 Jack Jumper Ant immunotherapy is only available in Tasmania, Victoria and South Australia despite the ants being present in other states and territories. The cost of immunotherapy is funded by the state governments in Victoria and Tasmania but not in South Australia. The treatment cost for immunotherapy in South Australia is very high:

The cost currently is about \$3,500 for the first year during the build-up phase, where you use more venom because you give it more frequently. Thereafter it is about \$2,500 per year for the next five years. It has already been said about the quality-of-life issues and the constant fear that people live in.<sup>83</sup>

2.91 A member of the eczema support group made the following comment about the costs of living with eczema:

Thousands of dollars spent on doctors' fees, prescription creams, moisturisers, different specialists & treatments, inability to work full time due to severe eczema. Not just a financial burden, but also costly in terms of just living a full life - loss of quality time with friends and family during flare-ups, being unable to travel to particular destinations with poor water hygiene due to high risk of bacterial skin infections, problems undertaking sweaty exercise because it triggers a flare, etc. there are so many costs to eczema.

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<sup>81</sup> Ms Maria Stipic, *Committee Hansard*, Melbourne, 18 November 2019, p. 4.

<sup>82</sup> Dr Mullins, *Submission 205*, p. 6.

<sup>83</sup> Dr Pravin Hissaria, Allergy and Immunologist, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 21.

In addition to financial costs other costs of allergies include absenteeism at work and school and giving up work/careers to look after children including home schooling children with severe and multiple allergies.<sup>84</sup>

- 2.92 Asthma Australia stated that the cost of anaphylaxis to Australian society is increasing. In a study commissioned by ASCIA in 2007, it found that anaphylaxis cost Australia upwards of \$7.78 billion.<sup>85</sup>
- 2.93 Asthma Australia commented that asthma, food allergy and anaphylaxis often occur together:

It was found that the combined cost of anaphylaxis and asthma in Australia cost \$30 billion. Medication costs alone related to allergic rhinitis (a condition linked with asthma) is itself estimated to cost Australia \$226.8 million in 2010. Currently 11.2 per cent of Australians have asthma and 18 per cent have allergic rhinitis, with a forecast 70 per cent increase in allergic disease in Australia by 2050.<sup>86</sup>

- 2.94 People living in regional and rural Australia highlighted their additional travel costs and loss of productivity in addition to the direct financial burden of allergies:

As our family lives in a rural area in NSW we have found that access to food allergy services are lacking. We have to travel three hours one way to receive services in relation to diagnosis, testing, management and treatment of food allergy for our daughter. This has a significant cost factor involved as it requires loss of work days, travel expenses and accommodation costs.<sup>87</sup>

### *Pharmaceutical Benefits Scheme (PBS) and accessibility*

- 2.95 The treatments for multiple allergies and non-food allergies can be expensive. The Committee received evidence that believed these high costs could be alleviated by adding more allergy treatments to the Pharmaceutical Benefits Schedule (PBS).
- 2.96 Professor O’Hehir stated:

...we're really fortunate that there are lots of excellent treatments for patients with allergic diseases, but relatively few of those are accessible on the

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<sup>84</sup> Eczema SUPPORT Australia, *Submission 172*, p. 6.

<sup>85</sup> Asthma Australia, *Submission 230*, p. 2.

<sup>86</sup> Asthma Australia, *Submission 230*, pp. 2-3.

<sup>87</sup> Name withheld, *Submission 216*, p. 2.

Pharmaceutical Benefits Scheme, and financial constraints often force patients to choose only what they can afford, which may put them at significant risk.<sup>88</sup>

2.97 ASCIA commented that many established, evidence-based treatments for allergic disease are registered with the Therapeutic Goods Authority (TGA), but are not listed on the PBS. Improving access to these treatments can improve the course of a person's disease and greatly improve quality of life. Many new treatments are emerging in this field and expert representation is needed for their evaluation.<sup>89</sup>

2.98 Professor O'Hehir suggested that expanding the availability of some allergy medications on the PBS would lead to improvements in health and would have long term economic benefits:

New biologics have the potential to offer excellent treatment for patients with disabling allergic conditions—such as eosinophilic oesophagitis, chronic sinusitis with nasal polyps, systemic mastocytosis, severe allergic eczema—and yet none of these is available to us at present on the Pharmaceutical Benefits Scheme, unlike the biologics that are available for qualifying patients with asthma and chronic hives. Expanding availability would not only improve health but also lead to educational and economic benefits. I do recognise the constraints on the Pharmaceutical Benefits Scheme, but with some health and economic evaluation I think there are opportunities there.<sup>90</sup>

2.99 The Western Australia Child and Adolescent Health Service commented that the costs associated with accessing certain treatment can also restrict access. Patients within the public system may receive subsidised treatment options, however access is limited and there are long waiting lists. It called for some allergy related medications to be listed on the PBS:

We would support Pharmaceutical Benefits Scheme listing of immunotherapy for aeroallergens and allergy related medications (e.g. antihistamines, asthma preventers, nasal sprays, dupilumab).<sup>91</sup>

2.100 A&AA highlighted the high financial cost of treatments for allergies:

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<sup>88</sup> Professor Robyn O'Hehir, Director, Department of Allergy, Immunology and Cystic Fibrosis; Alfred Health; Head of Department, Allergy, Clinical Immunology and Respiratory Medicine, Central Clinical School, Monash University, *Committee Hansard*, Melbourne, 18 November 2019, pp. 12-13.

<sup>89</sup> ASCIA, *Submission 153*, p. 4.

<sup>90</sup> Professor O'Hehir, *Committee Hansard*, Melbourne, 18 November 2019, p.13.

<sup>91</sup> Western Australia Child and Adolescent Health Service, *Submission 182*, p. 3.

Many disease states require multiple medications and daily treatments for optimal management, the financial cost of which is significant. The majority of medications for allergic disease are not PBS-listed and immunotherapy for environmental allergens such as house dust mite and pollens, which can cause severe allergic asthma, allergic rhinitis and eczema, are not within reach for many people, as they are too expensive.<sup>92</sup>

- 2.101 Dr Melanie Wong, from the Children’s Hospital Westmead, Sydney, raised the issue of high cost of treatment and the lack of access to newer therapies:

Even old treatments such as antihistamines, nasal steroids and immunotherapy—none of them are covered under PBS. So, again, low-income families who might otherwise be subsidised for payment of medications suffer. They may not be able to afford these medications, so that’s an issue. Moving on to the newer therapies, there are great therapies such as dupilumab—which is a good treatment for kids with severe eczema and asthma, and is recognised around the world as something that should be used as treatment—that we do not have access to in Australia. That needs to change.<sup>93</sup>

## Theories on what causes allergies

- 2.102 Research suggests that food allergy arises from a complex combination of genes and environmental factors that affect the normal maturation and development of the immune system.
- 2.103 The Committee asked many of the expert witnesses what they thought might be causing the increasing rate of allergies and anaphylaxis. Some of the hypothesis were put to the Committee with the proviso that a lot more research was needed in order to understand possible causes. Overwhelmingly, the Committee heard that the links to allergies were multifactorial.
- 2.104 Dr Rachel Peters from CFAR commented that the risk factors for food allergy include having eczema. There are studies underway looking at whether, if skin barrier function can be improved and eczema can be prevented in infancy, there would be a follow-on effect in preventing food allergy.<sup>94</sup>

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<sup>92</sup> A&AA, *Submission 184*, p. 1.

<sup>93</sup> Dr Melanie Wong, Head, Department Allergy and Immunology, The Children’s Hospital Westmead, Sydney, *Committee Hansard*, Sydney, 19 November 2019, p. 21.

<sup>94</sup> Dr Rachel Peters, Researcher and Team Leader, Centre for Food and Allergy Research, *Committee Hansard*, Melbourne, 18 November 2019, p. 28.

2.105 Professor Connie Katelaris of Campbelltown Hospital explained:

If you have a child with early onset eczema, we know that an emollient treatment to repair the skin barrier is essential to stop the ingress of allergens and the secondary setting up of allergic responses to those allergens.<sup>95</sup>

2.106 Dr Mark Hew of Alfred Hospital in Melbourne discussed the gene and environmental interaction that has been observed in relation to allergies:

There is a gene-environmental interaction that is identified in the work on asthma and also mirrored by the work in food allergy. Twenty-five per cent of Melbourne is Indian or Asian in origin. Forty per cent of Emergency Department presentations for thunderstorm asthma were Indian and Asian. So there was a markedly higher proportion of Indians and Asians for thunderstorm asthma. Of the patients who came to emergency, there were people who were sent home with milder disease and people who were admitted with more severe disease. The ones who were admitted were more likely to be second-generation Asian.

So we think there is not just an environmental problem but a combination between genetics and environment interacting explaining part of the increase in allergy rates in Australia and mirrored by the food story as well.<sup>96</sup>

2.107 This theory is also called the 'Asian migration hypothesis'. Dr Peters from CFAR commented:

We've shown in several different studies coming out of Melbourne that infants who live in Australia but have parents who were born in Asia have a higher risk of food allergy. Children who were born in Asia and subsequently moved to Australia have the lowest prevalence of food allergy. This finding has recently been replicated in the US as well, so they are seeing the same associations between migration from Asia to America that we are seeing in Australia.<sup>97</sup>

2.108 At this stage there is a loose hypothesis referred to as the 'Five D theory', about why severe allergies and anaphylaxis might be occurring. Dr Peters continued:

We sometimes refer to it as the 'five Ds'. These would be diet, dry skin—dry skin being eczema; diet being timely introduction of allergenic foods—dogs,

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<sup>95</sup> Professor Katelaris, *Committee Hansard*, Sydney, 19 November 2019, p. 43.

<sup>96</sup> Dr Mark Hew, Head of Allergy, Asthma and Clinical Immunology Service, Alfred Health, *Committee Hansard*, Melbourne, 18 November 2019, p. 21.

<sup>97</sup> Dr Peters, *Committee Hansard*, Melbourne, 18 November 2019, p. 29.

dirt or dribble, which relate to the external microbial environment, and vitamin D deficiency. These are all the factors that we know are related to the rising epidemic of food allergy.<sup>98</sup>

2.109 Professor Katelaris commented that research is pointing to a common factor that there has been a change in Australian diets which has changed the gut microbiome:

One of the basic ones that we're now coming back to is that there are things that have impacted our gut microbiome. Instead of having a varied and healthy gut microbiome from eating whole foods, grains, fruits and vegetables, we've had a restriction in the variety of foods and a lot of highly processed foods creeping into our diet, and that then has an impact on the development of the gut microbiome.

This probably starts with the mother and fetus interaction and carries through to early infancy. The other things that impact are the increased use of antibiotics, the so-called clean society, living in a very clean environment and the lack of contact between large animals and human beings now.<sup>99</sup>

## Data

2.110 The prevalence levels of allergies and anaphylaxis are estimated using a range of sources from various national surveys, research studies and hospital admission data from different states and territories. There is no central agency collating data on allergies and anaphylaxis.

2.111 The NAS commented on the lack of data for anaphylaxis and food and drug allergy:

The incidence of many allergic diseases in Australia, including anaphylaxis and confirmed severe drug allergy is currently unknown. There are no national mechanisms to alert consumers of potentially lethal allergen contamination in foods in a timely manner. Models for drug allergy registries exist globally.<sup>100</sup>

2.112 CFAR suggested that reporting of allergic reactions and anaphylaxis needs to be done in every state and territory. Currently only Victoria collects this data:

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<sup>98</sup> Dr Peters, *Committee Hansard*, Melbourne, 18 November 2019, p. 30.

<sup>99</sup> Professor Katelaris, *Committee Hansard*, Sydney, 19 November 2019, p. 42.

<sup>100</sup> ASCIA, *Submission 153*, p. 5.

We would definitely recommend that an improved registry is commenced in all states of Australia, and we believe that needs to be identifiable data so that we can understand who is getting anaphylaxis. And it needs to encompass not only the emergency department but within the hospital; if they have anaphylaxis, or if they present to any other healthcare professional such as the GP, it needs to be linked on from there. And then we can understand more about who is getting it and what the risk factors are for anaphylaxis. We can use that data to link to other databases to understand more about how to prevent, how to treat and how to predict severe reactions—and potentially who to target for our treatment programs, because we will target those who are at high risk.<sup>101</sup>

2.113 Many witnesses and submissions called for a national register for anaphylaxis. A national register would assist with research being undertaken to find out what might be causing the increasing rates of anaphylaxis in Australia.

2.114 A&AA supported the need for a national register to capture anaphylaxis data:

There is much that we can learn from a register that captures anaphylaxis events and fatalities. Deaths from anaphylaxis or suspected anaphylaxis need to be reported to the state coroner. The small number of coronial investigations and inquests have assisted A&AA, ASCIA (and therefore the NAS) in better supporting, informing, educating and guiding individuals, families, schools, camp facilities, food service establishments, sporting clubs and institutions, such as hospitals, in improving care and safety.<sup>102</sup>

2.115 In the past 12 months, Western Australia (WA) has documented its first two paediatric food allergy anaphylaxis fatalities. The Government of WA's Child and Adolescent Health Service commented:

We are not aware of previous recorded paediatric fatalities in WA but as there is no anaphylaxis register, we cannot confirm this.<sup>103</sup>

2.116 The Royal Hobart Hospital commented that Australia needs to 'support design, development and implementation of a nationwide allergy

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<sup>101</sup> Dr Kirsten Perrett, Chief Investigator, Centre for Food Allergy Research; Paediatric Allergist, Murdoch Children's Research Institute and Royal Children's Hospital, *Committee Hansard*, Melbourne, 18 November 2020, p. 26.

<sup>102</sup> A&AA, *Submission 184*, pp. 1-2.

<sup>103</sup> Government of Western Australia, Child and Adolescent Health Service, *Submission 182*, p.1.

information system to improve data collection and patient alert notifications.<sup>104</sup>

2.117 The Australian and New Zealand Anaesthetic Allergy Group (ANZAAG) stated that the development and maintenance of a perioperative anaphylaxis database would provide essential information to help answer the following questions to help optimise patient care. It suggested that an anaphylaxis database would be useful in collecting data on the following questions:

- What is the incidence of perioperative anaphylaxis in Australia and New Zealand?
- Which agents (drugs, antiseptics, surgical materials) are the common causes of perioperative anaphylaxis associated with surgery in Australia and New Zealand?
- Are particular agents associated with more profound anaphylaxis or death?
- Are there measures that could reduce the rate of intraoperative anaphylaxis such as the restriction of sale of pholcodine?
- Which treatments are most effective for the acute management of perioperative anaphylaxis?
- What is the most effective way to identify the cause of an episode of perioperative anaphylaxis?<sup>105</sup>

2.118 The NAS suggested that the Australian Government develop and implement an anaphylaxis register/notification scheme in every jurisdiction. NAS stated this register should:

- capture fatalities and near misses as a result of anaphylaxis;
- enable the swift removal of foods with incorrect allergen labelling from the market place;
- allow prompt investigation of food premises with unsafe food allergen management practices; and
- allow for pooled de-identified national data.<sup>106</sup>

## **Committee comment**

2.119 The Committee is concerned to learn that Australia's already high rates of food allergies and anaphylaxis are continuing to rise and that without an

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<sup>104</sup> Jack Jumper Allergy Program, *Submission 169*, p. 4.

<sup>105</sup> ANZAAG, *Submission 116*, p. 3.

<sup>106</sup> NAS, *Submission 118*, p. 6.

understanding of what is causing this, the numbers will continue to increase. The inquiry brought to the Committee's attention the social and economic burden that allergies and anaphylaxis are having on individuals and families.

- 2.120 The Committee notes the strain on the health care sector in terms of long waiting lists to access allergy specialists, the high financial cost of allergies to individuals, families and the economy and the enormous impact that allergies have on people's quality of life and mental health, especially for those living with severe allergy such as eczema and anaphylaxis.
- 2.121 The Committee acknowledges the high financial costs for people living with one or more allergies. The Committee is concerned that allergies are costing thousands of dollars each year for multiple medical appointments, scripts, skin barrier creams, inhalers and specific non-allergen foods. In addition, the Committee notes the common occurrence of loss of income due to the need for many parents to oversee their child's allergy management and safety. The Committee believes the Australian Government should consider the best way to provide financial assistance to people and families living with allergies, with consideration given to providing carers with a carers allowance or assessing the eligibility for a healthcare card.
- 2.122 It is evident that significant health and economic gains can be made by improving research into the prevention, diagnosis, treatment and management of allergies. However the first step is to ensure that Australia has a robust national data collection for anaphylaxis, to better understand the extent of the issue.
- 2.123 The Committee is concerned that deaths and near misses continue to occur due to the mismanagement of anaphylaxis. Data collection is clearly an issue that needs to be addressed immediately if Australia is to continue to conduct meaningful research into allergies and anaphylaxis. The lack of a national data collection for the presentation of, near misses and deaths from anaphylaxis should be addressed immediately.
- 2.124 The Committee believes that the Australian Government should consider the expansion of the Centre for Allergy and Research (CFAR) to establish a National Centre for Allergy and Anaphylaxis. The National Allergy Strategy (NAS) and the Australasian Society of Clinical Immunology and Allergy (ASCIA) would be able to assist the Australian Government for advice in establishing the national centre.
- 2.125 The National Centre for Allergy and Anaphylaxis would ensure there was a national standardised approach to allergy management by developing and

implementing a Shared Care Model and a Clinical Care Standard for anaphylaxis. This clinic would be funded to carry out clinical research trials into food allergy treatments in addition to research to find a cure for severe allergies and anaphylaxis.

- 2.126 Consideration should be given to expanding the current work being undertaken by the Centre for Food and Allergy Research. Establishing a National Centre for Allergy and Anaphylaxis would require ongoing funding from the Australian Government.
- 2.127 The collation of data for anaphylaxis episodes and deaths should be provided to the national centre. This would require cooperation from all hospitals including data input and shared data from coroner's findings from all states and territories.
- 2.128 The collection of data for drug allergies including perioperative allergy in Australia would also require funding and cooperation from all hospitals in all states and territories. The benefits would greatly outweigh the costs in the long term.
- 2.129 The Committee was impressed to hear of the excellent research that has been undertaken on ticks, in particular, the research carried out by Professor van Nunen and colleagues on Mammalian Meat Allergy (MMA). The Committee considers it a priority for further funding to be allocated for research into tick allergy, anaphylaxis and cross sensitivity.

## **Recommendation 1**

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- 2.130 The Committee recommends that the Australian Government work with the states and territories to establish a National Centre for Allergies and Anaphylaxis in Australia, to ensure there is a national standardised approach to allergy management.**

## **Recommendation 2**

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- 2.131 The Committee recommends that the Australian Government dedicate additional funding into food allergies and anaphylaxis research, in particular funding for:**
- **the Centre for Food and Allergy Research (CFAR) so it can continue its work past 2022 (if Recommendation 1 has not been implemented by expanding CFAR to become a National Centre for Allergies and Anaphylaxis);**

- **clinical research into food allergy treatments (including allergies outside of peanut allergy) in particular into food based oral immunotherapy, including head-to-head trials (trials with no placebo);**
- **research into emerging allergic diseases such as eosinophilic oesophagitis and food protein-induced enterocolitis syndrome (FPIES);**
- **research into the social and psychological effects of allergies and anaphylaxis; and**
- **establishing a national register for anaphylactic episodes and death.**

### **Recommendation 3**

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**2.132 The Committee recommends that the Australian Government consider providing a healthcare card to people with severe and chronic allergic conditions and a carers allowance for their carers where appropriate.**



# 3. Supporting allergies in Australia

## Overview

- 3.1 The Committee received overwhelming evidence that the management and treatment standards for allergies and anaphylaxis are not consistent throughout Australia.
- 3.2 In addition to inconsistent management of allergies by medical specialists, many individuals suffering from allergies had to endure long waiting lists to seek professional advice whilst living with a potentially life threatening condition.
- 3.3 Some of the issues that will be discussed in this chapter include:
  - work currently undertaken by the Department of Health;
  - access to specialists and treatment in regional and rural Australia;
  - food allergy management;
  - drug allergy management; and
  - sting allergy management.

## Government partnerships

- 3.4 The Australian Government's Department of Health recognises the significant impact allergy and anaphylaxis place on the quality of life and overall health of individuals and their families, as well as the burden these conditions place on Australia's health system.
- 3.5 The Department provides 'ongoing support for the implementation of many of the actions in the National Allergy Strategy, including prevention

initiatives, support for young people with allergies, and the development of standards and guidelines for management of allergy and anaphylaxis.<sup>1</sup>

- 3.6 The NAS is a partnership between the Australasian Society of Clinical Immunology and Allergy (ASCIA), the leading medical and patient support organisations in Australia and Allergy and Anaphylaxis Australia (A&AA), a peak national charity health advisory body. The NAS document was developed with key stakeholder organisations and provides an overarching framework for a national response to the rise in allergic diseases. It identifies the most effective ways to:
- address allergic disease as a chronic disease and manage it with a public health approach;
  - provide an effective and coordinated plan to guide future actions to optimise the management of allergic diseases in Australia; and
  - improve the health and quality of life of people with allergic diseases, their carers and the community.<sup>2</sup>
- 3.7 The NAS received some funding from the Australian Government which has allowed them to undertake a number of projects, including the 250K Youth Project<sup>3</sup> and the Food Service Project<sup>4</sup>.
- 3.8 The NAS told the Committee that ‘While we have been successful in engaging with the relevant target groups and providing resources and support, there is still a lot of work that needs to be done in these areas.’<sup>5</sup>
- 3.9 The NAS was asked by the Department of Health to undertake some scoping work, relating to better recognition and management of drug allergy and the development of a shared care model for allergic diseases. Recommendations for drug allergy management were submitted to the Department of Health in 2017, and recommendations regarding a Shared Care Model for allergic diseases were finalised and submitted in December

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<sup>1</sup> Department of Health (DoH), *Submission 78*, p. 4.

<sup>2</sup> National Allergy Strategy (NAS), *Submission 118*, p. 2.

<sup>3</sup> 250K youth project provides ongoing education to teens and young adults about eating out with food allergy.

<sup>4</sup> Food Service Project is an e-training course available for cooks and chefs to help improve food allergen management in food service, including camps.

<sup>5</sup> Ms Sandra Vale, NAS, *Committee Hansard*, Sydney, 19 November 2019, p. 12.

2019.<sup>6</sup> The findings in these two reports are confidential and hence information from them has not been included in this report.

## Access to treatment

- 3.10 The evidence highlighted the critical need for more timely and equitable access to quality care for patients with allergic disease. Many people reported long waiting times to see specialists, both for public and private specialist allergists and immunologists.<sup>7</sup>
- 3.11 Some personal accounts described how long waiting times exacerbated their or their child's conditions and led to delays in getting correct medical advice.<sup>8</sup> Others reported that long wait times led to delays in access to adrenaline auto-injectors as these devices can only initially be prescribed by an allergy specialist.<sup>9</sup>
- 3.12 The Committee was told that long wait lists for patients to see allergy specialists sometimes resulted in patients seeking help from practitioners who were not adequately trained. This may lead to potential harm, additional healthcare encounters, increased costs and burden on the health system. The NAS stressed that:

Access to appropriate care is often delayed with long waiting times to see the relevant medical specialist/s and has resulted in patients receiving inappropriate advice from alternative/unorthodox health practitioners. Absence of appropriate care carries a significant risk of serious adverse events and increases healthcare encounters and associated costs as well as the use of unproven therapies.<sup>10</sup>

- 3.13 ASCIA commented that timely and quality care is particularly important for infants:

Timely access to quality care for infants and young children with suspected food allergy is particularly important as it can prevent food allergy and

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<sup>6</sup> Ms Vale, NAS, *Committee Hansard*, Sydney, 19 November 2019, p. 12.

<sup>7</sup> Name withheld, *Submission 19*, p. 3; Name withheld, *Submission 221*, p. 1; Mrs Sally Pokoney, *Submission 135*, p. 5; Name withheld, *Submission 150*, p. 2; Name withheld, *Submission 152*, p. 2.

<sup>8</sup> Mrs Sarah Dubravica, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 2.

<sup>9</sup> Mrs Chelsea Taylor, private capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 7.

<sup>10</sup> NAS, *Submission 118*, p. 4.

anaphylaxis, reduce unnecessary food restrictions and decrease the risk of nutritional and growth problems.<sup>11</sup>

- 3.14 Many of the public hospitals across Australia informed the Committee that they have long waiting lists and that they do their best to triage the most critical patients.
- 3.15 For example, the WA Child and Adolescent Health Service stated that ‘there are currently over 2000 children on the waitlist for their first immunology clinic appointment at public hospitals in Western Australia, with patients waiting between 12 weeks to five years based on their postcode and hospital catchment zone.’<sup>12</sup>
- 3.16 The Royal Children's Hospital in Melbourne, which remains the only public service for paediatric allergy in Victoria, commented that the waiting list times for allergy evaluation and food challenges was around six to seven months.<sup>13</sup>
- 3.17 Dr Melanie Wong of The Children's Hospital at Westmead, Sydney commented:

We have insufficient public hospital allergy clinics. Although we have urgent patients who are squeezed in by our overloaded staff – and we actually triage our referrals so that we only see the more complex end of the spectrum of disease – we have a waiting period of at least six months. If you're a young child, that six months is a long wait.<sup>14</sup>

- 3.18 Dr Patrick Quinn of The Women's and Children's Hospital, Adelaide, commented that:

We have more than 1,100 children on our public waiting list with median wait times of more than a year to be seen. And these are median wait times, so some of those children are waiting two or three years or more to see us. The

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<sup>11</sup> Australasian Society of Clinical Immunology and Allergy (ASCIA), *Submission 153*, pp. 2-3.

<sup>12</sup> Western Australia Child and Adolescent Health Service, *Submission 182*, p. 2.

<sup>13</sup> Dr Joanne Smart, Director, Department of Allergy and Immunology, Royal Children's Hospital, *Committee Hansard*, Melbourne, 18 November 2019, p. 13.

<sup>14</sup> Dr Melanie Wong, Head, Department of Allergy and Immunology, The Children's Hospital at Westmead, Sydney, *Committee Hansard*, p. 20.

long public waiting times disproportionately affect those most disadvantaged in our community and those with the most complex clinical needs.<sup>15</sup>

3.19 Professor Connie Katelaris of Campbelltown Hospital commented:

...last year we saw 3,200 children in consultation at Campbelltown Hospital in our paediatric immunology and allergy clinic. We have 385 children on our food challenge waiting list, and, with present resourcing, on average a two-year wait for a food allergy challenge in our hospital setting.<sup>16</sup>

3.20 Professor Peter Smith commented that private practice waiting lists are just as long as some of the public hospitals:

There is a nine month wait at a private allergy clinic in Queensland for food challenges and an 18 month waitlist to see me... and somewhere between nine months and two years in a public hospital.<sup>17</sup>

3.21 Dr Hew from Alfred Health suggested that some states fund inadequate placements for immunologists in the public hospitals:

My suggestion is that there is no good funding mechanism that allows the hospitals to take up allergy procedures within Victoria. Hospitals decide funding, and these procedures are fairly low priority based on the hospital KPIs of keeping inpatients out of hospital.<sup>18</sup>

3.22 Dr Wong also noted the insufficient funding levels provided to public hospitals for allergy specialists:

There's been an exponential increase in the number of children with allergic disease, and also the complexity of that disease, over the last 20 to 30 years. Resourcing of hospital services hasn't kept up with this increasing need.<sup>19</sup>

## City, regional and rural perspectives

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<sup>15</sup> Dr Patrick Quinn, Paediatric Allergist and Clinical Immunologist and Medical Unit Head, Department of Allergy and Clinical Immunology, The Women's and Children's Hospital, *Committee Hansard*, Adelaide, p. 7.

<sup>16</sup> Professor Connie Katelaris, Head of Unit, Immunology and Allergy, Campbelltown Hospital, *Committee Hansard*, Sydney, 19 November 2019, p. 40.

<sup>17</sup> Prof Peter Smith, Allergist and Director, Allergy Medical Group, *Committee Hansard*, Brisbane, 18 February 2020, p. 16.

<sup>18</sup> Dr Mark Hew, Head of Allergy, Asthma and Clinical Immunology Service, Alfred Health, *Committee Hansard*, Melbourne, 18 November 2019, p. 15.

<sup>19</sup> Dr Wong, *Committee Hansard*, Sydney, 19 November 2019, p. 20.

3.23 The Committee received evidence that highlighted the lack of access to allergy specialists in regional and rural Australia. ASCIA commented:

The issue of timely and equitable access to quality care for patients with allergic disease is critical. At present many parts of Australia, particularly regional, rural and remote areas, are underserved in terms of the availability of clinical immunology/allergy specialists.<sup>20</sup>

3.24 Dr Adriana Le also raised concerns about the lack of allergy specialist services facing rural and regional Australia:

Timely access to specialist allergy services is an issue in both urban and regional/rural settings in Australia, but is particularly poor for the latter, with a shortage of allergy specialists and health professionals with allergy expertise in these locations.

The current model of allergy care in Australia is urban based and often requires regional and rural patients to travel long distances, including interstate, for specialist care. While it is obviously not practical to have an allergy specialist located in every rural location, ensuring there is adequate provision for allergy specialists in major regional public hospitals is a key part of improving rural allergy care.<sup>21</sup>

3.25 Dr Le continued:

In many rural locations, while it would not be practical to have a private allergist working full time, periodic visits by an allergist would fulfil an important area of need. However, unlike other specialties such as cardiology and psychiatry, there is currently no support, subsidies or incentives (such as even travel and accommodation grants) for private allergists to visit these areas.<sup>22</sup>

3.26 Professor Douglass noted that in Victoria 'Just under 20 per cent of patients are from outside the metropolitan regions...I think rural and remote patients are at a disadvantage. We do run quite an active telehealth service, and that's great. I always like to see the patient once, but after that you can usually do it by telehealth'.<sup>23</sup>

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<sup>20</sup> ASCIA, *Submission 153*, p. 2.

<sup>21</sup> Dr Ariana Le, *Submission 254*, p. 1.

<sup>22</sup> Dr Ariana Le, *Submission 254*, p. 1.

<sup>23</sup> Professor Jo Douglass, Head, Department of Clinical Immunology and Allergy, The Royal Melbourne Hospital, *Committee Hansard*, Melbourne, 18 November 2019, p. 19.

- 3.27 Professor Douglass discussed the merits of telehealth to assist in providing a solution to this issue facing many people with allergies in Australia:

It seems to me that telehealth is an option. Even for patients that could be seen—there are a lot of tests you could do on the blood. Maybe not everyone has to come down to Melbourne, because it costs patients to come down. Despite transport access schemes, it's a lot.

- 3.28 She also advocated for a more determined public outreach program to increase knowledge and understanding of allergies and anaphylaxis:

I think upskilling and educating the rural GP workforce would be really important. Unlike asthma, where there has been outreach, with the National Asthma Campaign and Asthma Council Australia going out and getting asthma care out there, I think allergy and anaphylaxis care has not been so well done. We all know about asthma-friendly schools. That's educated everyone, from laypeople up. It isn't the same with allergy. It could be done. A similar resource still exists, and the network is there to do it.<sup>24</sup>

- 3.29 The Australian College of Nurses commented that they have an important role to play in providing better access to allergy patients throughout Australia:

Development of a variety of nursing roles as suggested in the National Allergy Strategy can only enhance and improve care for those with an allergy, or those who experience allergy induced anaphylaxis. That role is especially significant in rural and remote areas where a registered nurse is often the only health care practitioner available.<sup>25</sup>

- 3.30 Inquiry participants reported that they had applied, often multiple times, for government assistance such as the carer's allowance or health care cards but had suffered from lengthy delays or been found ineligible.<sup>26</sup>

## ***Improvements to services***

### *Shared Care Model*

- 3.31 The NAS has undertaken work for the Department of Health that outlines how a Shared Care Model could assist patients with allergies and

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<sup>24</sup> Professor Douglass, *Committee Hansard*, Melbourne, 18 November 2019, p. 19.

<sup>25</sup> Australian College of Nursing (ACN), *Submission 124*, p. 1.

<sup>26</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 2; Name withheld, *Submission 17*, p. 2; Name withheld, *Submission 51*, p. 3; Name withheld, *Submission 87*, p. 2; Name withheld, *Submission 48*, p. 2; Name withheld, *Submission 185*, p. 1.

anaphylaxis in Australia to receive improved care and better and more timely access to all allergy services. The Shared Care Model 'is a patient centred approach to ensuring that the right care by the right health professional is received at the right time in the right place.'<sup>27</sup>

- 3.32 Australians with allergic diseases face many challenges in accessing quality health care in a timely manner, particularly those living in rural and remote areas. There is no quick-fix Shared Care Model. The model that is going to improve access to quality health care requires engagement with many key stakeholder organisations and will need to address multiple issues, including education for both health professionals and consumers. Ms Vale commented:

The National Allergy Strategy believes that a shared care model for allergy is not simply the upskilling of primary healthcare providers in allergy, as this does not recognise the complexity of the problem and will not achieve the desired outcomes.<sup>28</sup>

- 3.33 A Shared Care Model would improve access to care for allergy patients particularly in rural and remote areas. The Australian Paediatric Society (APS) supported the NAS Shared Care Model that was put forward at a forum in Sydney in April 2019. The APS stated:

The guiding principles of a Shared Care Model requires it to be patient-centred, safe, quality evidenced-based care. It should support health professionals with consultation collaboration and communication, with a clearly defined referral pathway and support. It also needs to be effective, efficient, accessible including the use of telemedicine, and supports integrated care with localised flexibility.<sup>29</sup>

- 3.34 In order to make this work and attract quality medical staff to regional and rural areas the APS commented that the Australian Government should:

Increase the loading of the Medicare rebate for clinical services in rural and remote Australia to assist people to afford treatment and to attract quality medical staff to areas where people with allergy do not have the financial resources to cover the Medicare gap payment.<sup>30</sup>

- 3.35 Dr Richard Loh, immunologist and allergy specialist, commented:

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<sup>27</sup> Ms Vale, National Allergy Strategy, *Committee Hansard*, Sydney, 19 November 2019, p. 12.

<sup>28</sup> Ms Vale, National Allergy Strategy, *Committee Hansard*, Sydney, 19 November 2019, p. 12.

<sup>29</sup> Australian Paediatric Society (APS), *Submission 84*, p. 3.

<sup>30</sup> Australian Paediatric Society (APS), *Submission 84*, p. 3.

To progress a Shared Care Model for allergic diseases we will also require leadership and commitment at the highest levels at Commonwealth, State, and Territory as no minister in any one jurisdiction can solve this epidemic of allergic diseases. We must avoid cost shifting, duplication, gaps in service delivery, or an unwillingness of any single government to take leadership for delivering a shared care model for allergic diseases.<sup>31</sup>

- 3.36 Professor Douglass discussed the fact that allergies are a national problem and therefore allergy care should be federally mandated. Professor Douglass suggested that 'If you had a federal standard of care for allergy, it would be incredibly helpful.'<sup>32</sup>

*Clinical care standards for anaphylaxis*

- 3.37 The Committee received evidence from specialists and people affected by allergies who called for a nationally consistent pathway or Clinical Care Standards for anaphylaxis to be agreed to and regulated.

- 3.38 The NAS commented that Clinical Care Standards would be a critical component of an effective Shared Care Model. Ms Vale commented:

In particular, we would like to see a Clinical Care Standard for the acute management of anaphylaxis developed as an urgent priority by the Australian Commission on Safety and Quality in Health Care. Despite having multiple national guidelines for anaphylaxis management in Australia since 2011, deaths from anaphylaxis continue to occur due to failures in diagnosis, inappropriate treatment and lack of appropriate management of the patient on discharge. Unlike guidelines, a Clinical Care Standard linked to hospital accreditation requires auditing and accountability.

Currently, in Australia, there is no requirement to report anaphylaxis deaths to the coroner. In addition, we have limited ability to capture information about anaphylaxis events in hospitals and the community, as we have inconsistent education of health professionals in the recognition of anaphylaxis and there are no nationally accepted diagnostic criteria.<sup>33</sup>

- 3.39 Dr Loh advocated for national Clinical Care Standards on allergies and anaphylaxis. He emphasised the benefits of a nationally consistent Clinical Care Standard:

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<sup>31</sup> Dr Richard Loh, *Submission 206*, p. 2.

<sup>32</sup> Professor Douglass, *Committee Hansard*, Melbourne, 18 November 2019, p. 21.

<sup>33</sup> Ms Vale, NAS, *Committee Hansard*, Sydney, 19 November 2019, p. 12.

These documents would provide summary statements on key areas of clinical practice for a specific condition where there is evidence of variation from best practice.

They are based on evidence contained in clinical guidelines. Clinical guidelines, such as ASCIA's and Victoria's anaphylaxis guidelines, detail all aspects of treatment and care for anaphylaxis. They are broader and extensive. Deaths from anaphylaxis in Australia (Mullins, 2016) continue to rise despite guidelines. In order to address this issue, Clinical Care Standards for Anaphylaxis need to be developed and implemented to stop this variation from best practice.<sup>34</sup>

3.40 The NAS discussed the benefits of Clinical Care Standards as opposed to the current anaphylaxis management guidelines:

The existing anaphylaxis management guidelines, and there are several available across Australia, do not have indicators that assist local health services to monitor the quality of implementation. A national Clinical Care Standard does not exist but would help to address many of these issues.<sup>35</sup>

*Mental health*

3.41 Parents of infants and children who have severe allergies and anaphylaxis told the Committee of the anxiety, stress and trauma that they live with when caring for children with anaphylaxis.

3.42 Many parents of children with allergies who participated in the inquiry reported feelings of anxiety, depression, distress and fear for their children.<sup>36</sup> Some went as far as to say that the emotional cost was worse than the financial cost.<sup>37</sup>

3.43 Many inquiry participants reported that living with allergy was highly socially isolating.<sup>38</sup> Eczema sufferers in particular reported very high rates of depression, feelings of hopelessness, and even suicidal thoughts.<sup>39</sup>

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<sup>34</sup> Dr Richard Loh, *Submission 206*, p. 2.

<sup>35</sup> NAS, *Submission 118*, p. 6.

<sup>36</sup> Dr Prathyusha Sanagavarapu, private capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 4; Name withheld, *Submission 73*, p. 1; Name withheld, *Submission 73*, p. 1; Name withheld, *Submission 95*, pp. 2-3; Allergy Support Hub, *Submission 109*, p. 1; Name withheld, *Submission 150*, p. 1; Ms Nikki Brown, *Submission 9*, p. 1.

<sup>37</sup> Mrs Nelson, private capacity, *Committee Hansard*, Brisbane 18 February 2020, p. 8.

<sup>38</sup> Mrs Nelson, private capacity, *Committee Hansard*, Brisbane 18 February 2020, p. 1; Miss Wong, private capacity, *Committee Hansard*, Sydney 19 November 2019, p. 7; Ms Roelandts, private

My father also had eczema later in life. He lived in a rural area and didn't have access to treatment. The day that he went to the doctor and was told that there was no further treatment is the day we lost him to suicide. I do not blame his doctors for what happened—they didn't know any better. That's a big loss. After my dad died we found that he actually had exposed bone where he had scratched through. But that wasn't looked at when he went to the doctor—because they didn't know that it could be that bad. This was somebody who had suffered for many, many years without access to treatment and with no awareness in the community. It was a loss that could have been avoided.<sup>40</sup>

- 3.44 Many parents reported that their children also suffered from anxiety<sup>41</sup> and that this could occur in very young children who might not even understand their feelings.<sup>42</sup>
- 3.45 Adults with allergies reported bullying in the workplace and workplaces not making allowances for a person's allergies.<sup>43</sup>
- 3.46 Some people reported experiencing trauma from being poorly cared for by paramedics immediately after an episode of anaphylaxis.<sup>44</sup>
- 3.47 Many inquiry participants gave evidence of how helpful therapy had been for them.<sup>45</sup>
- 3.48 Ms Jenny Murtagh described how the anxiety that comes with having a child or being a child with severe food allergies can be overwhelming, and noted that with the benefit of hindsight:

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capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 7; Name withheld, *Submission 199*, p. 2; Name withheld, *Submission 246*, p. 3; Name withheld, *Submission 49*, p. 2; Eczema Support Australia, *Submission 172*, p. 5; Name withheld, *Submission 22*, p. 1; Name withheld, *Submission 162*, p. 2; Name withheld, *Submission 157*, p. 1.

<sup>39</sup> Ms Funk, Eczema Support Australia, *Committee Hansard*, Brisbane, 18 February 2020, p. 26; Eczema Support Australia, *Submission 172*, p. 4; Name withheld, *Submission 177*, p. 1.

<sup>40</sup> Ms Layton, Eczema Support Australia, *Committee Hansard*, Brisbane, 18 February 2020, pp. 29-30.

<sup>41</sup> Ms Cheminant, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 4; Mrs Gray, ausEE Inc., *Committee Hansard*, Brisbane, 18 February 2020, p. 22; Name withheld, *Submission 79*, pp. 1-2; Name withheld, *Submission 95*, pp. 2-3; Name withheld, *Submission 98*, p. 1.

<sup>42</sup> Mrs Argenio, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, pp. 4-5.

<sup>43</sup> Name withheld, *Submission 1*, pp. 1-2; M Post, *Submission 39*, p. 2.

<sup>44</sup> Ms Gray, ausEE Inc., *Committee Hansard*, Brisbane, 18 February 2020, p. 24.

<sup>45</sup> Ms Gray, ausEE Inc., *Committee Hansard*, Brisbane, 18 February 2020, p. 22; Name withheld, *Submission 77*, p. 2.

...counselling being offered to parents of newly diagnosed children would have been wonderful, and also for children themselves as they navigate through to their teens and early adulthood. The hypervigilance that is required is exhausting for the sufferer and for their families, and there is a level of social isolation that comes about.

Socialising in our society almost always involves eating, and it is sometimes easier to just avoid being a part of it, which is sad for young people. Severe reactions can cause post-traumatic stress issues for the patient and their family. Having a counsellor who understands these issues could be useful (although I'm sure my son would not avail himself of such a service at this stage of his life, so again an earlier childhood start would be good).<sup>46</sup>

3.49 Ms Hagiliassis explained that after her son suffered a severe reaction in 2016, she went into post-traumatic stress. She told the Committee:

I felt like our doctors and specialists let us down in terms of carers, and there was no referral to seek any support from an emotional perspective.<sup>47</sup>

3.50 This led Ms Hagiliassis to create a charitable organisation called Anaphylaxis Network Australia, that provides online support for parents with children who have allergies and may have had an anaphylactic reaction.<sup>48</sup>

#### *Adrenaline auto-injectors (EpiPens)*

3.51 In Australia, after a specialist has diagnosed risk of anaphylaxis or after an anaphylactic episode, patients are usually prescribed two subsidised scripts for adrenaline auto-injectors. Each adrenaline auto-injector costs approximately \$80 each or \$40 when subsidised on the PBS.

3.52 Many individuals and organisations raised concerns in relation to adrenaline auto-injector (EpiPens) shortages in Australia<sup>49</sup>. The Committee heard that these shortages occur intermittently but when there is a shortage it becomes critical and life threatening for many people who need to replace out-of-date EpiPens.

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<sup>46</sup> Ms Jenny Murtagh, *Submission 89*, p. 2.

<sup>47</sup> Mrs Joanne Hagiliassis, Director, Anaphylaxis Network Australia, *Committee Hansard*, Melbourne, 18 November 2019, p. 33.

<sup>48</sup> Mrs Hagiliassis, *Committee Hansard*, Melbourne, 18 November 2019, p. 33.

<sup>49</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 2; Pharmaceutical Society of Australia, *Submission 69*, p. 3; Name withheld, *Submission 218*, p. 1; Name withheld, *Submission 171*, p. 2; Mrs Simone Albert, *Submission 37*, p. 1.

3.53 Ms Emily Marney outlined this problem in her submission:

Numerous times I have gone to fill a prescription for EpiPens, more commonly after I have used our previous ones so need them replaced that day, and I have been told they are out of stock with the supplier and unsure when they will be back in stock. This has therefore left me with an allergic child and no lifesaving medication. I have been known to call all pharmacies in the 100km radius to find any pharmacy with available EpiPens and have been willing to travel, but had no luck. When the EpiPens would finally come back in stock they would have short expiry's, some dated only 4 months away. This then left me spending \$40 on an EpiPen to then have to replace it in 4 months' time again when there could potentially be a shortage again. I am exhausted with playing roulette with my child's life.<sup>50</sup>

3.54 Many submitters wrote about having to visit several pharmacies trying to find an EpiPen,<sup>51</sup> being limited to one EpiPen per person due to shortages and having to rely on expired or close to expired pens.<sup>52</sup>

3.55 Numerous submissions commented that the number of government subsidised EpiPens which people can access is inadequate. Many parents reported having to buy more than two pens a year in order to supply schools with an individual EpiPen for their child, plus wanting to have injectors available in their homes and in person when going out which can become a financial burden given the expense of non-PBS prescribed adrenaline auto-injectors.<sup>53</sup>

With the required EpiPen supply at home as being two in the instance that the first EpiPen fails, as well as requiring additional EpiPens for the school AND for the after-school care program our daughter attends, we incur a total cost of approximately \$260 per year to purchase four EpiPens (two on prescription at a reduced cost, and two at full over the counter cost without a prescription). Anaphylaxis management means we have no choice but to purchase this life saving medication. The EpiPen prescription allowance per patient needs to be

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<sup>50</sup> Ms Emily Marney, *Submission 212*, p. 2.

<sup>51</sup> Ms Morton, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 42, Ms Marney, *Submission 212*, p. 2; Name withheld, *Submission 185*, p. 5, Name withheld, *Submission 170*, p. 1.

<sup>52</sup> Mrs Teresa Nielsen, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 5; Name withheld, *Submission 199*, p. 6; Ms Sue Williams, *Submission 67*, p. 1, Name withheld, *Submission 19*, p. 3; Name withheld, *Submission 231*, p. 1; Ms Carly Morton, *Submission 183*, p. 1.

<sup>53</sup> Name withheld, *Submission 13*, p. 1; Name withheld, *Submission 171*, p. 2; Name withheld, *Submission 19*, p. 2; Dr Michelle Warton, *Submission 224*, p. 1; Name withheld, *Submission 192*, p. 1; Name withheld, *Submission 98*, p. 3; Name withheld, *Submission 80*, pp. 1-2.

increased to four per year at a reduced cost to allow families to purchase this medication without the financial burden of hundreds of dollars per year...<sup>54</sup>

3.56 A&AA made the following comment in relation to the shortages:

Currently, Australia only has one brand of adrenaline auto-injector (EpiPen). There have been several EpiPen shortages with the most significant being in 2017/2018. The impact on individuals at risk of anaphylaxis, A&AA, ASCIA, the Therapeutic Goods Administration, pharmacies and Mylan Australia was huge. The safety of individuals at risk of anaphylaxis was compromised with people being asked to rely on expired devices, parents and childcare staff not giving the EpiPen when indicated because of fear they would not be able to replace it, and ill-informed health professionals showing people how to use ampoule, needle and syringe.<sup>55</sup>

3.57 A&AA suggested the following issues should be taken into consideration when making an alternative available in Australia:

Make alternative adrenaline auto-injectors available to Australians with potentially life-threatening allergy. Serious consideration needs to be given to the doses available (i.e. is there a dose for infants or a dose for those 60 kg and over?), the size and shape of the device and how easily it can be carried (especially by males, who do not generally carry hand bags), needle length (shorter needles may not penetrate into the muscle for quick absorption of adrenaline), and temperature control in Australia's hot climate.<sup>56</sup>

## Food allergy management

3.58 The food challenge is the gold standard used for food allergy diagnosis. Many individual submitters and medical professionals commented that waiting times for food challenges in public hospitals are unacceptably long.<sup>57</sup> Food challenges are not only important for diagnosing initial food allergies but they are used to confirm whether patients have outgrown their allergies throughout their lifetime.

3.59 The Melbourne Allergy Centre and Children's Specialist described the food challenge process:

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<sup>54</sup> Name withheld, *Submission 13*, p. 1.

<sup>55</sup> A&AA, *Submission 184*, pp. 18-19.

<sup>56</sup> A&AA, *Submission 184*, p. 19.

<sup>57</sup> Maria Stipic, *Submission 18*, p. 1; Ms Jenny Murtagh, *Submission 89*, p. 2.

A food challenge is the process by which small, incremental quantities of a food allergen is given to a patient. The purpose of a food challenge is to determine whether a child is either truly allergic to the food, or if food allergy has resolved, and the child is now able to tolerate the food. Arguably, food challenges are the most important assessment tool that we have as allergists.

Food challenges are highly labour-intensive and require constant supervision throughout the challenge. During a challenge, the patient is given increasing doses of the food at 15-20 minutely intervals. The patients have nursing observations performed every 15-20 minutes and are being constantly observed during this period. The doctor also frequently reviews the patient throughout the course of the challenge. A typical challenge takes approximately 4-5 hours to complete, but can be much longer if the patient reacts or if they have anaphylaxis, which will involve a further 4 hour observation period.<sup>58</sup>

3.60 Dr Joanne Smart explained the reason why food challenges are resource intensive, as patients need to be monitored in an appropriately resourced setting in case there is an anaphylactic reaction to the food challenge:

In our hands, at the children's hospital and also in some private settings, generally 20 to 25 per cent of food challenges result in an allergic reaction. The majority of these are mild to moderate and managed simply with antihistamine or steroid. But two per cent—and this is unpredictable—result in anaphylaxis requiring adrenaline.<sup>59</sup>

3.61 Dr Smart also told the Committee that she had put in an application to the Australian Government to request a Medical Benefits Scheme (MBS) allergy item number for food challenges that was unsuccessful.<sup>60</sup>

3.62 Dr Mullins highlighted food challenge logistics in his submission and discussed some of the existing barriers to improving waiting lists for food challenges:

- the availability of facilities, such that most public hospitals have wait lists of over 12 months to do so;
- reliance on state health departments to fund these facilities within their current budgets; and

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<sup>58</sup> Melbourne Allergy Centre and Children's Specialist, *Submission 237*, p. 2.

<sup>59</sup> Dr Smart, *Committee Hansard*, Melbourne, 18 February 2019, p. 14.

<sup>60</sup> Dr Smart, *Committee Hansard*, Melbourne, 18 February 2019, p. 12.

- the costs of doing so given the absence of any specific Medicare item number for food or drug challenges.<sup>61</sup>

3.63 CFAR raised the issue of access equity noting that there is an acute lack of publically available access to allergy management specialists. Dr Smart commented:

It seems to me that the disproportionate availability of public allergy services really disenfranchises and disadvantages particularly those of lower socioeconomic status throughout our state who are unable to utilise private providers. And the gaps in care for things like private allergy testing and the availability of that are substantial, so it is a great concern to me.<sup>62</sup>

*Access to Food Oral Immunotherapy (OIT)*

3.64 After a food allergy diagnosis has been confirmed, there are limited treatments available for food allergy sufferers. Food allergen avoidance is currently the only recommendation in Australia. There are limited clinical research food oral immunotherapy (OIT) trials occurring in Australia.

3.65 The Committee received evidence from allergy sufferers and their families calling for immediate access to food OIT in Australia. At present, families are travelling to the United States to access food OIT treatments which comes at considerable expense. One witness estimated the cost of travelling to the United States for a four week food OIT treatment was 'just over \$20,000 for everything: the accommodation, the flights, the transport while we were there and the doctor's fee.'<sup>63</sup>

3.66 CFAR outlined the reasons why food oral immunotherapy is not yet available in Australia. Dr Perrett commented:

OIT is an emerging, experimental treatment and refers to feeding an allergic individual increasing amounts of food they're allergic to with the goal of increasing the threshold to which triggers a reaction. This is known as 'desensitisation' and desensitisation is a temporary state. It does occur in the majority of children and adults who undergo food oral immunotherapy but there are significant safety concerns.

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<sup>61</sup> Dr Mullins, *Submission 205*, pp. 7-8.

<sup>62</sup> Dr Smart, *Committee Hansard*, Melbourne, 18 February 2019, p. 15.

<sup>63</sup> Ms Catherine Sly, *Committee Hansard*, Brisbane, 18 February 2020, p. 7.

We do not believe food oral immunotherapy is ready to be offered in the clinic setting (in Australia). But these trials and studies have taught us so much and we believe we are now ready to act in Australia.<sup>64</sup>

3.67 Dr Perrett explained to the Committee that food oral immunotherapy puts people into remission rather than cure:

Essentially, when we are talking about treatments for food allergy, we are talking about this temporary desensitisation state whereby if you consume the food allergen that you are allergic to regularly, on a daily basis, you have raised the threshold such that you shouldn't have a reaction below that threshold. We do know that that is a temporary state and it does change as your immune system changes. This is the tricky thing about immunotherapy. If you have a fever or an infection, or if it is during your menstruation or you do exercise or your temperature is overheated, you may have a lower threshold that you react to. This is why we have a lot of ongoing reactions with people on immunotherapy.<sup>65</sup>

3.68 Further information on OIT research is discussed in chapter 5.

## **Drug allergy management**

3.69 Australia does not have an adequate drug and medicine allergy management strategy. ASCIA informed the Committee that 'if Australia can improve its drug allergy management it would lead to preventable deaths from drug allergy.'<sup>66</sup>

3.70 The NAS provided the Department of Health with a scoping paper on drug allergy management. The NAS urged the Australian Government to fund and implement all recommendations.<sup>67</sup>

3.71 The Pharmacy Society of Australia (PSA) informed the Committee that 'Pharmacists have a considerable role in supporting patients and carers in the management or treatment of allergies and anaphylaxis. This may be in relation to patient medicines or medication management, as well as

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<sup>64</sup> Dr Kirsten Perrett, Chief Investigator, Centre for Food and Allergy Research; and Paediatric Allergist, Murdoch Children's Research Institute and Royal Children's Hospital, *Committee Hansard*, 18 November 2019, pp. 23-24.

<sup>65</sup> Dr Perrett, *Committee Hansard*, 18 November 2019, p. 25.

<sup>66</sup> ASCIA, *Submission 153*, p. 16.

<sup>67</sup> NAS, *Submission 118*, p. 7.

education, advice and support provided on various health conditions which may span a spectrum of complexity.’<sup>68</sup>

3.72 Pharmacists may obtain information on a patient’s drug allergy status (or contribute this information to their record) through a number of ways, for example:

- patient’s My Health Record;
- patient’s dispensing or medication supply record;
- in the context of a recommendation of an over-the-counter medicine;
- during a medication management review (e.g. MedsCheck service, Home Medicines Review) consultation; and
- other pharmacist-delivered health service.<sup>69</sup>

3.73 The PSA commented that maintaining drug allergy information and sharing between different healthcare professionals and settings (with patient consent) are important in order to deliver optimal care to a patient. The PSA added that ‘increasing uptake and use of the My Health Record will, in part, facilitate this process going forward.’<sup>70</sup>

3.74 The PSA informed the Committee that there will soon be improvements to labelling some allergens in medicines.

Currently substances in medicines that need to be declared currently include gluten, lactose, peanuts and tartrazine. PSA understands that under the new rules there will be a longer list of substances that must be declared on a label if they are present in the medicine. Additional substances required to be declared include crustacea, fish, eggs, soya, milk and tree nuts.

PSA is supportive of this initiative and has commenced advising pharmacists about the changes so that patients and carers can be supported and educated appropriately.<sup>71</sup>

### ***Antibiotic avoidance and drug de-labelling***

3.75 Antibiotic avoidance due to an unsubstantiated belief in having a drug allergy is an increasing issue in Australian medical care. The Committee received evidence about antibiotic avoidance and the urgent need to ‘de-label’ patients from their unproven drug allergies in Australia.

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<sup>68</sup> Pharmaceutical Society of Australia (PSA), *Submission 69*, p. 3.

<sup>69</sup> PSA, *Submission 69*, p. 3.

<sup>70</sup> PSA, *Submission 69*, p. 3.

<sup>71</sup> PSA, *Submission 69*, p. 3.

- 3.76 The NAS stated that around 25 per cent of patients in hospitals report having drug allergies, usually to antibiotics, however studies have found only 10 per cent of those claiming to have a drug allergy are truly allergic. This unnecessary avoidance can have a significant effect on antimicrobial stewardship and can prevent patients from receiving the best treatment for their illnesses.<sup>72</sup>
- 3.77 Dr William Smith of the Royal Adelaide Hospital has done a survey of the adult population in South Australia which showed that 22 per cent of the population reported an allergy to one or more drugs, 13 per cent reported an allergy to one or more antibiotics, and 9.3 per cent reports an allergy to penicillin.<sup>73</sup>
- 3.78 Dr Smith said this is concerning, as published studies have shown between 90 and 98 per cent of the population have no penicillin allergy and can take it safely.<sup>74</sup>
- 3.79 Dr Sara Barnes wrote that antibiotic allergy de-labelling allows more targeted treatment and reduces the use of broad spectrum antibiotics. Dr Barnes commented:

This benefits not just the individual patients but also has flow-on effects to the rest of the Australian healthcare system in the form of reduced hospital stays for common infections, reduced antimicrobial resistance and less incidences of clostridium difficile (a disease of the large intestine caused by the bacterium clostridium difficile, appearing usually after recent antibiotic use<sup>75</sup>).<sup>76</sup>

- 3.80 Dr Barnes continued:

There are many reasons a person might believe they are allergic to a certain drug when they are not. A person may experience adverse symptoms while taking a drug. In some cases this is a true allergic reaction to the medication (and such medication should be avoided), but in many cases the person has experienced adverse symptoms due to the illness they had at the time, such as

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<sup>72</sup> NAS, *Submission 118*, p. 7.

<sup>73</sup> Dr William Smith, Senior Consultant, Head of Unit, Department of Clinical Immunology and Allergy, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 13.

<sup>74</sup> Dr Smith, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 13.

<sup>75</sup> SA Health, 'Clostridium difficile infection (CDI)' <<https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/Health+topics/Health+conditions+prevention+and+treatment/Infectious+diseases/Clostridium+difficile+infection+CDI/>> viewed 13 February 2020.

<sup>76</sup> Dr Sara Barnes, *Submission 125*, p. 1.

a rash caused by virus being mistaken for a reaction to prescribed antibiotics. In other cases, a person may continue to report drug allergies based on childhood reactions which the person has outgrown or based on more spurious information, such as a family member having the same allergy.<sup>77</sup>

3.81 Dr Smith expanded on this, saying that false antibiotic labelling tends to ‘metastasise’:

...what starts out as a minor rash with amoxicillin becomes, after a while, an allergy to all penicillins, which, later on—because people don't remember the initial event—gets called an anaphylaxis to penicillins, and that later forces avoidance not only of all penicillins but also of cephalosporins...because there's a theoretical cross-reaction rate. So if you see somebody who has a label of penicillin allergy and you don't know how bad the allergy was, you just tend to avoid all of those antibiotics, which puts the person at a disadvantage.<sup>78</sup>

3.82 The NAS recommended the creation of a national standardised drug allergy de-labelling guideline in order to confirm people’s drug allergy status. It also recommended that the Australian Government create a new Medicare Benefits Schedule (MBS) item number for drug allergen challenges.<sup>79</sup>

3.83 The NAS gave evidence that such a program would reduce costs by allowing medical professionals to prescribe ‘basic, safe and cheap’ drugs which might otherwise be avoided unnecessarily.<sup>80</sup> This would result in shorter hospital stays, reduced complications and would reduce the rate of antibiotic resistance in the community.<sup>81</sup>

3.84 Professor Brendan Murphy, Chief Medical Officer of the Department of Health emphasised the importance of scientifically validating allergies and said he hoped clinics for antibiotic allergy de-labelling would be set up in public hospitals.<sup>82</sup>

3.85 Dr Smith of the Royal Adelaide Hospital gave evidence that drug de-labelling is being carried out in hospital allergy and immunology clinics and other specialist clinics but with a very limited capacity. He went on to say

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<sup>77</sup> NAS, *Submission 118*, p. 20.

<sup>78</sup> Dr Smith, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 14.

<sup>79</sup> NAS, *Submission 118*, p. 7

<sup>80</sup> NAS, *Submission 118*, p. 20.

<sup>81</sup> NAS, *Submission 118*, p. 20.

<sup>82</sup> Prof Murphy, DOH, *Committee Hansard*, Canberra, 24 October 2019, p. 5.

that there were a large number of people who would be eligible for 'low risk de-labelling' which could be performed in other medical settings if there were clinical guidelines for other doctors to follow.<sup>83</sup>

- 3.86 The Royal Hobart Hospital has commenced an antibiotic allergy clinic. Mrs Jennifer Gudden of the Royal Hobart Hospital said that this work is important to the community but the service is currently unfunded and unsustainable for the hospital.<sup>84</sup>
- 3.87 Professor Jo Douglass at the Royal Melbourne Hospital said that although drug allergy de-labelling is important to the community, it is rarely available in the public health system.<sup>85</sup>
- 3.88 Professor Douglass said further that there are international models for drug de-labelling which can be done effectively and cheaply, but these models require resourcing.<sup>86</sup>
- 3.89 Professor Dominic Mallon wrote that inaccurate drug allergy labelling can lead to patients not being prescribed the most effective medications which in turn leads to further impacts on patient care and the overall efficacy of the health system.<sup>87</sup>
- 3.90 The APS confirmed that unnecessary drug avoidance is an issue particularly in regional Australia and that it would support protocols or professional programs to address the problem.<sup>88</sup>
- 3.91 A paramedic stated that many of their patients confuse drug side effects with allergy to certain drugs. This is often an issue of education between the patient and their medical practitioner but has the follow on effect of that patient not being able to receive the drug which would be most effective for their medical needs. This leads to allergies being taken less seriously by the

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<sup>83</sup> Dr Smith, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 14.

<sup>84</sup> Mrs Gudden, Royal Hobart Hospital, Tasmanian Health Service, *Committee Hansard*, Adelaide, 17 February 2020, p. 22.

<sup>85</sup> Prof Jo Douglass, Head, Department of Clinical Immunology and Allergy, the Royal Melbourne Hospital, *Committee Hansard*, Melbourne, 18 November 2019, p. 15.

<sup>86</sup> Prof Jo Douglass, the Royal Melbourne Hospital, *Committee Hansard*, Melbourne, 18 November 2019, p. 21.

<sup>87</sup> Prof Mallon, *Submission 83*, p. 4.

<sup>88</sup> Australian Paediatric Society, *Submission 84*, p. 3.

wider community and viewed as an inconvenience rather than a serious medical condition.<sup>89</sup>

- 3.92 The Australian College of Nursing (ACN) commented that ‘drug allergy labelling is a particular area of concern for nurses as they deliver the majority of direct care to patients. The ACN recommended that the Australian Commission on Safety and Quality in Health Care (ACSQHC) develop an Allergy/Anaphylaxis Clinical Care Standard which would set out consistent national management standards for drug allergy. It also recommended a national database for recording food and drug allergies, working on a similar model to the Australian Immunisation Registrar (AIR).<sup>90</sup>
- 3.93 The ACN practitioners wrote that health professionals need more training in the assessment of allergy to prevent antibiotic allergy labelling. It commented further that the overprescribing of antibiotics in medical practice needs further attention.<sup>91</sup>
- 3.94 The Government of Western Australia Child and Adolescent Health Service noted:
- ...that the most commonly reported drug allergy is to penicillin, with 18 per cent of adults and between five and eight per cent of children reporting having a penicillin allergy, though most of these people are avoiding it unnecessarily. Patients who report this allergy have increased rates of morbidity and mortality. The WA Government recommended the creation of national guidelines for drug allergy confirmation as well as increased national education about drug allergies.<sup>92</sup>
- 3.95 A&AA stated that health professionals and consumers are generally not well informed about true drug allergy. It said:

Accurate diagnosis of drug allergy can be difficult without adequate and skilled investigation. Health professionals are very aware of poor outcomes when an individual with true drug allergy has the medication, so they rarely question consumers who say they are allergic when they are not, for fear of getting it wrong. With antibiotic allergy, the truth around the label of

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<sup>89</sup> Name withheld, *Submission 102*, p. 4.

<sup>90</sup> ACN, *Submission 124*, pp. 5-6.

<sup>91</sup> Australian College of Nurse Practitioners (ACNP), *Submission 158*, p. 4.

<sup>92</sup> Child and Adolescent Health Service, Government of Western Australia, *Submission 182*, p. 3.

antibiotic allergy is generally not questioned until a person is in a compromised situation where the drug of choice cannot be used.<sup>93</sup>

- 3.96 Dr Richard Loh stated that there needs to be a larger emphasis on drug allergy de-labelling in health care. He went on to say that all patients reporting a drug allergy, particularly for antibiotics, should undergo diagnostic evaluation to determine if the allergy is real. Skin testing and oral drug challenges are methods that can be used to determine drug allergy.<sup>94</sup>
- 3.97 Migraine Australia supported the implementation of accurate and affordable drug allergy diagnosis in the Australian health care system. Effective migraine management often requires rotating several medications to avoid the side effects of medication overuse. As such, unconfirmed drug allergy which limits the medications of a patient can make migraine management more difficult.<sup>95</sup>
- 3.98 The Royal Adelaide Hospital Department of Immunology performed a study on self-reported drug allergy, in particular penicillin, and found that 90 per cent of respondents to the survey were good candidates for de-labelling.<sup>96</sup>
- 3.99 Dr Smith of the Royal Adelaide Hospital stated that testing a person for drug allergy with the aim to de-label them from the allergy would involve skin prick testing and then drug challenges administered over the course of a day for higher risk patients.<sup>97</sup>
- 3.100 Dr Smith also gave evidence that after a person is de-labelled the problem becomes removing that allergy label from their medical records in other health facilities. He said that My Health Record could be an excellent resource for recording the results of patient de-labelling.<sup>98</sup>
- 3.101 Dr Birgit Marchand, a Paediatric Allergist and Immunologist from the Queensland Allergy Service suggested that, until some sort of universal medical record was set up showing a person's drug allergy de-labelling, a medic-alert type bracelet identifying that a person has been de-labelled from

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<sup>93</sup> A&AA, *Submission 184*, p. 24.

<sup>94</sup> Dr Richard Loh, *Submission 206*, p. 4.

<sup>95</sup> Migraine Australia, *Submission 215*, p. 3.

<sup>96</sup> Immunology Department, Royal Adelaide Hospital, *Submission 140*, p. 3.

<sup>97</sup> Dr Smith, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 15.

<sup>98</sup> Dr Smith, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 17.

their drug allergy would be an option for emergency situations where a person may not be able to confirm their de-labelling.<sup>99</sup>

3.102 The Royal Adelaide Hospital Department of Immunology made several suggestions for the implementation of any national drug allergy de-labelling program:

- national guidelines should be developed for drug allergy evaluation;
- low-risk drug allergy de-labelling procedures should be developed for usage in a variety of medical settings;
- Medicare items should be developed to encourage drug allergy testing in private medical care settings;
- hospital resources should be allocated to drug allergy testing facilities (i.e. Nursing, pharmacy and specialist resources); and
- electronic health records such as My Health Record should facilitate the recording of drug allergy reaction information, as well as current de-labelling status.<sup>100</sup>

## Sting allergy management

3.103 In addition to food and drug allergies, the Committee heard that insect allergy is on the rise in Australia. Stings from bees, wasps and ants can result in anaphylaxis.

3.104 Dr Pravin Hissaria, Immunologist and Allergist, Clinical Immunology and Allergy Department, Royal Adelaide Hospital, commented that bee sting anaphylaxis is common but treatable in Australia. He stated:

Honey bee venom allergy is the major cause of insect sting anaphylaxis in southern and south-eastern Australia. Venom immunotherapy for the treatment of stinging insect anaphylaxis involves the administration of increasing doses of purified insect venom with the aim of inducing clinical tolerance.<sup>101</sup>

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<sup>99</sup> Dr Birgit Marchand, Paediatric Allergist and Immunologist, Queensland Allergy Service, *Committee Hansard*, Brisbane, 18 February 2020, p. 15.

<sup>100</sup> Immunology Department, Royal Adelaide Hospital, *Submission 140*, p. 5.

<sup>101</sup> Dr Pravin Hissaria, Immunology/allergy consultant/specialist, Clinical Immunology and Allergy Department, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 19.

- 3.105 Dr Hissaria said that ‘because honey bee venom allergy is prevalent worldwide, there are commercially available venom extracts which are subsidised on the PBS for immunotherapy.’<sup>102</sup>
- 3.106 Immunotherapy is not yet available for treating tick allergy or reactions triggered by other species of ants and wasps.

### *Venom desensitisation programs – Jack Jumper Ants*

- 3.107 Jack Jumper Ants are found in southern areas of Australia and there is currently only limited access to Jack Jumper Ant venom immunotherapy in Tasmania, South Australia and Victoria. However, Jack Jumper Ants are found in parts of New South Wales (NSW), and Australian Capital Territory (ACT), Queensland (QLD) and Western Australia (WA). Jack Jumper Ants are increasingly contributing to anaphylaxis admissions to hospitals.
- 3.108 Research into Jack Jumper Ants commenced in 2001 with a successful clinical trial at the Royal Hobart Hospital looking into ant venom allergy research:

In the ten years prior to the establishment of the Jack Jumper Allergy Program, there were four reported deaths from anaphylaxis to Jack Jumper Ant stings. There have been no documented deaths to Jack Jumper Ant sting anaphylaxis since the Program began in 2001.<sup>103</sup>

- 3.109 The research team at Royal Hobart Hospital have developed a lifesaving venom immunotherapy treatment for people with severe Jack Jumper Ant venom allergy. The Committee heard that ‘what started as a small research project has developed into a program providing venom immunotherapy treatment to anaphylactic patients across three states.’<sup>104</sup>
- 3.110 The Tasmanian Jack Jumper Allergy Program (JJAP) is an example of Government support for innovative health care services that have had real benefits for patients and the community at a national level.<sup>105</sup>
- 3.111 The Committee heard from several hospitals and community groups about the Jack Jumper Ants and the allergy management strategy that is available in Tasmania, Victoria and South Australia only. The Committee was told

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<sup>102</sup> Dr Hissaria, *Committee Hansard*, Adelaide, 17 February 2020, p. 20.

<sup>103</sup> Jack Jumper Allergy Program, *Submission 169*, p. 1.

<sup>104</sup> Jack Jumper Allergy Program, *Submission 169*, p. 1.

<sup>105</sup> Jack Jumper Allergy Program, *Submission 169*, p. 1.

there is currently only limited access to Jack Jumper Ant venom immunotherapy.

- 3.112 Access to venom immunotherapy clinics is vital for patients who are anaphylactic to Jack Jumper Ants. The fear and anxiety that the risk of anaphylaxis can create is significant:

Educating patients around their allergy is of vital importance, however we must ensure GPs are supported with information and education around available services and have clear pathways for referrals.<sup>106</sup>

- 3.113 The Royal Hobart Hospital is the only manufacturer of Jack Jumper Ant venom worldwide. The capacity of the Royal Hobart Hospital to produce venom immunotherapy products affects all states in treating patients.

- 3.114 Demand for services in both insect venom allergy assessment and Venom Immunotherapy (VIT) is high. In Tasmania, there are currently 90 people medically assessed by the JJAP waiting to commence VIT. This equates to more than one year wait for some patients to start treatment. Many patients remain at very high risk of further stings, anaphylaxis and subsequent hospital admissions. Referrals are increasing, however the ability to treat patients is restricted by lack of resources to support demand and service growth.<sup>107</sup>

- 3.115 The JJAP told the Committee:

Tasmania is the only state or territory in Australia that does not have an integrated and coordinated Allergy and Immunology service. It has an outstanding team of dedicated staff and volunteers that have achieved the goal of developing a scientifically-proven treatment strategy for patients with Jack Jumper Ant venom allergy.<sup>108</sup>

- 3.116 Researchers at Royal Adelaide Hospital have collaborated closely with the Royal Hobart Hospital in Jack Jumper Ant venom research for many years and currently have two clinical trials underway. South Australia offers a Jack Jumper Ant Venom Immunotherapy clinic through Royal Adelaide Hospital, however unlike Tasmania and Victoria, South Australian patients

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<sup>106</sup> Jack Jumper Allergy Program, *Submission 169*, p. 2.

<sup>107</sup> Jack Jumper Allergy Program, *Submission 169*, p. 3.

<sup>108</sup> Jack Jumper Allergy Program, *Submission 169*, p. 3.

have been funding their own treatment. As such, treatment was cost prohibitive for many patients.<sup>109</sup>

- 3.117 As of July 2019, the Royal Adelaide Hospital began absorbing the high cost of VIT through its own budget however this is a precarious way to fund a valuable program and it takes funding away from other important programs. Dr Hissaria told the Committee:

...in the last six months, we have actually put in an application to the hospital and most likely the hospital pharmacy is going to fund it, but it is going to come out of the clinical immunology and allergy budget, which, as you can imagine, is very low, and this might take up the whole budget. We won't be able to treat any other immunological conditions even if we wanted to so it is going to be a significant strain on that.<sup>110</sup>

- 3.118 Dr Adriana Le described the prevalence levels of sting presentations in South Australia and discussed the regions around Australia where Jack Jumper Ants are found.

In Tasmania, the Jack Jumper Ant is the most common cause for anaphylaxis presentation in hospital. In South Australia the most common presentation in our venom allergy clinic is still around 60 per cent bee venom. That means one-third of presentations are for Jack Jumper Ants and only a minority are for wasps. It's the dominant cause of anaphylaxis in South Australia and actually in other areas of Australia.

The ant is very endemic in Tasmania but it's widespread in the Adelaide Hills. It's found on Kangaroo Island. It's found in the southern parts of the area like the York Peninsular. It's found throughout the ACT and NSW where treatment is not accessible. It can even be found in WA and Queensland. So it is a national issue.<sup>111</sup>

### *Manufacturing the venom extracts*

- 3.119 The Royal Hobart Hospital Jack Jumper Allergy Program is licensed by the TGA to manufacture standardised Jack Jumper Ant venom extracts for immunotherapy in the form of Active Pharmaceutical Ingredients (API). API

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<sup>109</sup> Jack Jumper Allergy Program, *Submission 169*, p. 3.

<sup>110</sup> Dr Hissaria, *Committee Hansard*, Adelaide, 17 February 2020, p. 20.

<sup>111</sup> Dr Adriana Le, Immunology/allergy consultant/specialist, Clinical Immunology and Allergy Department, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 23.

is manufactured locally in Hobart and provides lifesaving treatment to patients in Tasmania, Victoria and South Australia.<sup>112</sup>

- 3.120 Manufacture of Jack Jumper Ant Venom Immunotherapy products is an extremely labour intensive process:

Manufacture of each batch involves manual collection of thousands of stinging ants from bushland areas within Tasmania where these ants are known to be abundant, followed by dissection of ant venom sacs under microscope, sterile manufacturing processes in a Pharmacy Clean Room, followed by extensive quality control testing before release. The Royal Hobart Hospital aims to maintain standardised Jack Jumper ant venom extracts price as low as practicable, however the increasing costs of TGA licensing and quality control activities must be met.<sup>113</sup>

- 3.121 Pharmaceutical companies have shown little interest in manufacturing this product, likely due to the market being limited to Australia, which negatively impacts their return on investment.<sup>114</sup>

### **Committee comment**

- 3.122 The Committee was concerned to hear so much evidence about the lack of access to allergy specialists throughout Australia. Whilst the Committee understands that the funding of hospitals is a state and territory issue, the Committee urges these jurisdictions to review the evidence and consider a long term strategy to fund and manage the workforce demand for allergy and immunology specialists. Over time this will alleviate the pressures and long waiting lists if more funding of specialists is provided for in public hospitals across Australia.
- 3.123 The Committee believes there is merit in the National Allergy Strategy working with the Australian Government and states and territories to roll out a national Shared Care Model for allergy management.
- 3.124 Clinical Care Standards for the acute care of anaphylaxis should be implemented alongside a shared care model. The Australian Commission on Safety and Quality in Health Care should work with the National Allergy Strategy and the Australian Government to agree on National Clinical Care Standards for the acute care of anaphylaxis.

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<sup>112</sup> Jack Jumper Allergy Program, *Submission 169*, p. 2.

<sup>113</sup> Jack Jumper Allergy Program, *Submission 169*, p. 2.

<sup>114</sup> Jack Jumper Allergy Program, *Submission 169*, p. 2.

- 3.125 The Committee believes it is important for Australia to have a national standard to report anaphylaxis deaths to the coroner in all states and territories. Such a referral will assist with the development of a robust national data collection for anaphylaxis.
- 3.126 The Committee was concerned to hear evidence suggesting inconsistent discharge practices were taking place across Australia from Emergency Departments for patients suffering from anaphylaxis. The Committee believes patients should receive a script for an adrenaline auto-injector, a referral to see a specialist between 4-6 weeks after discharge, and a referral to a counsellor or psychologist trained in the area of anaphylaxis trauma.
- 3.127 For people suffering from anaphylaxis for the first time, patients and carers of patients should receive information about the seriousness of anaphylactic reactions and should receive referrals to counsellors and psychologists as required.
- 3.128 The Committee was impressed with the educational resources available on the ASCIA website for patients, carers, consumers, school staff, early childhood education/care staff, first aid providers and healthcare workers. The Committee encourages ASCIA to promote these resources to relevant sectors, including in newborn information packs for new parents.
- 3.129 Drug allergy management is an area of concern that is getting little attention despite the significant health issues that arise from drug allergy mismanagement, including preventable deaths. The Committee supports the creation of a drug allergy database and standardised clinical drug allergy education and training for all medical staff. The National Allergy Strategy has put forward recommendations to the Department of Health in a Drug Allergy Project. The Committee urges the Australian Government to consider funding the implementation of recommendations in the National Allergy Strategy Drug Allergy Project.
- 3.130 The Committee is concerned by the high incidence of drug de-labelling, particularly for antibiotics, and the effects this can have on the community in the form of increased antimicrobial resistance, increased hospital stays, and reduced patient outcomes. It is very important that people be de-labelled from unconfirmed drug allergies, such as penicillin.
- 3.131 The Committee believes that a public health based drug allergy de-labelling program and associated education campaign would be an important step to reducing drug de-labelling. In chapter 2 the Committee recommended the creation of a national anaphylaxis and severe drug allergy register. The drug

de-labelling program would need to feed its data into the National Centre for Allergies and Anaphylaxis.

- 3.132 The Committee was impressed by the innovative research and treatment programs that have been developed in Tasmania to treat Jack Jumper Ant allergy. The Committee believes it is important that the Royal Hobart Hospital receives ongoing funding from the Australian Government for this uniquely Australian problem. In addition, the Committee believes that the venom immunotherapy treatment should be available in all states and territories as required as a nationally funded program.

#### **Recommendation 4**

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- 3.133 **The Committee recommends that the Australian Government work with all states and territories to provide a consistent national framework for patients being discharged from an Emergency Department after an anaphylactic reaction. These patients should be provided with the following:**

- **an adrenaline auto-injector script for up to a maximum of 3 adrenaline auto-injectors and an appropriate emergency action plan (including digitised action plans) as per the Australasian Society of Clinical Immunology and Allergy (ASCIA)'s recommendation;**
- **if not already diagnosed with anaphylaxis, the patient should be given a priority referral (this referral must be for the period four to six weeks after discharge) to an immunologist or allergy specialist; and**
- **information pamphlets on allergies and anaphylaxis. For example, information that outlines support and information on allergies from peak bodies such as ASCIA and Allergies and Anaphylaxis Australia (A&AA).**

#### **Recommendation 5**

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- 3.134 **The Committee recommends that the Australasian Society of Clinical Immunology and Allergy (ASCIA) receive ongoing long term funding to continue its partnership work with the Department of Health and the National Allergy Strategy, to develop minimum standards of allergy training for health professionals including:**

- funding for the promotion of the e-resources ASCIA has already developed to all relevant communities throughout Australia;
- minimum standards of allergy training in the curriculum for all university medical schools and training of general practitioners, physicians and paediatricians, nurse practitioners, psychologists, dieticians, and paramedics; and
- funding support for ASCIA to provide training for all health professionals listed above.

### **Recommendation 6**

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3.135 The Committee recommends that the Australian Government provide telehealth funding support for doctors and allied health workers in order to provide professional services and support to allergy patients in rural, regional and remote Australia.

### **Recommendation 7**

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3.136 The Committee recommends that the Australian Government consider an Medical Benefits Scheme (MBS) item number for food challenges carried out by appropriate clinicians.

### **Recommendation 8**

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3.137 The Committee recommends that the Australian Government provides funding for a public health system drug de-labelling program including:

- developing a program in the public health system to run community education campaigns to encourage people to participate in drug allergy de-labelling programs;
- create clinical guidelines for drug allergy de-labelling; and
- give consideration to the need for a Medicare Benefits Scheme (MBS) item number for drug allergy testing and drug allergy challenges.

### **Recommendation 9**

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3.138 The Committee recommends that the Australian Government should mandate consistent labelling for all products containing chlorhexidine,

iodine and latex to ensure consumers and healthcare workers can readily identify these products. In addition:

- alternatives for chlorhexidine, iodine and latex should be readily available;
- all government procurement should maintain a database of all chlorhexidine, iodine and latex containing products;
- the broader healthcare sector should be educated about the risks of anaphylaxis to chlorhexidine, iodine and latex.

### **Recommendation 10**

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3.139 The Committee recommends that the Australian Government provide additional funding support to ensure the Royal Hobart Hospital can provide ongoing Jack Jumper Ant venom immunotherapy treatment to Australians in all states and territories.

### **Recommendation 11**

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3.140 The Committee recommends that the Australian Government work with states and territories to ensure that all allergy and anaphylaxis fatalities receive an automatic referral to the coroner for assessment.

### **Recommendation 12**

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3.141 The Committee recommends that the Australian Government work with the Therapeutic Goods Administration (TGA) to:

- proactively encourage competition for pharmaceutical companies to supply alternative adrenaline auto-injectors to the Australian market in order to prevent future shortages;
- investigate the expiry dates of adrenaline auto-injectors; and
- investigate reasons for intermittent supply of adrenaline auto-injectors.

## **Recommendation 13**

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**3.142 The Committee recommends that the Australian Government work with states and territories to:**

- **review the sufficiency of the current allergist and immunologist workforce in hospitals throughout Australia; and**
- **ensure that there is funding for increased placements of these specialists in all hospitals (if a need is found).**



# 4. Food and drug labelling, education and training and food services

## Overview

- 4.1 Food labelling in Australia has been scrutinised closely in recent times as food allergies have been on the rise. Food Standards Australia New Zealand (FSANZ) is an independent statutory authority that lies within the Department of Health and develops and maintains food standards within Australia and New Zealand. FSANZ has undertaken several rounds of public consultation to consider ways to improve current food labelling.
- 4.2 Severe allergies and anaphylaxis is not well understood in the general community or across the health sector. The inquiry found that more education and training is required for all doctors, specialists and allied health care workers who work with people suffering from allergies. This approach of further education and training extends into the food service industry.
- 4.3 This chapter discusses the following issues:
  - food and drug labelling;
  - upskilling medical experts and allied health sector workers in allergies and anaphylaxis; and
  - the need to make changes in the food service industry to support people with allergies and anaphylaxis.

## Food labelling in Australia

- 4.4 The Committee received a significant amount of evidence in relation to food labelling and the difficulties that this causes for people with food allergies. A consistent theme was that food labels need to be accurate and meaningful:

As a parent of a child who has multiple food allergies, I am depending on the accuracy of the manufacturer's food allergen statement. It can be a matter of life or death if the food allergen statement is incorrect.

Food shopping for a toddler who is anaphylactic to a number of allergens can be difficult and challenging when deciphering whether a product is safe for my child to consume as manufacturers rarely list the 7 top allergens by their common names (milk, egg, etc.). It is most common for manufacturers to list other/ name derivative names of food allergens. For example, casein and whey is another name/derivative for milk.<sup>1</sup>

- 4.5 Witnesses also highlighted inconsistent labelling as one of the most significant issues regarding labelling:

Possibly the greatest frustration is multiple names for the same thing: sometimes labelled as the substance name, sometimes labelled as a number, sometimes labelled as group or class of substance. For example: potassium sorbate, 202, or the more general 'contains sorbates'. Vague descriptors like 'spices' render foods unavailable to many unnecessarily. It would be better to have one standard required presentation of the name, and when applicable, number, on listed ingredients. It should also be required for those ingredients to be available when shopping online: some websites have ingredients listed, some do not, and some are inconsistent.<sup>2</sup>

- 4.6 In particular, there were many reports of difficulties with identically packaged items having different formulations and ingredients.<sup>3</sup>
- 4.7 Vigilance is required every time a product is bought from the supermarket that may contain allergens:

Over time our approach to food has become increasingly vigilant as we see more food products subject to recalls due to undeclared allergens. This has affected our level of confidence and trust across the food industry, where poor labelling and manufacturing processes are placing children and adults with anaphylaxis at high risk of life-threatening reactions.

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<sup>1</sup> Name withheld, *Submission 103*, p. 2.

<sup>2</sup> Migraine Australia, *Submission 215*, p. 1.

<sup>3</sup> Mrs Simone Albert, *Food Allergy Goals, Committee Hansard*, Melbourne, 18 November 2019, p. 9; Name withheld, *Submission 231*, p. 2; Mrs Pokoney, *Submission 135*, p. 3; Name withheld, *Submission 226*, p. 3; Ms Helen Marrero, *Submission 59*, p. 1; Name withheld, *Submission 136*, p. 2.

To compound this, manufacturers change ingredients in what was previously a 'safe' product without warning or advice, making the product now unsafe. Due to personal experience, we now check every food label every time we purchase a product. For e.g. maltodextrin can be derived from both wheat and corn and this can alternate between different batches often depending on where the product is made.<sup>4</sup>

- 4.8 One inquiry participant reported their child had had a reaction to ingredients which were not labelled on the package of a food item, the manufacturer refused to provide further information about the ingredients as it was 'proprietary information'.<sup>5</sup>
- 4.9 Another family suggested they had a triple check system for food purchases:

We have a three-point system of checking labels at the supermarket, as we put it in the cupboard and as we use them.<sup>6</sup>

- 4.10 Australia and New Zealand were among the first countries to recognise the need to regulate food allergens with the introduction, in 2002, of mandatory declaration requirements in the Australia and New Zealand Food Standards Code. Since 2002, the food industry in Australia and New Zealand has developed a number of best practice initiatives to support companies to manage food allergen risk and provide clear information to consumers in order to assist them to make informed choices.<sup>7</sup>

- 4.11 The Australian Institute of Food Science and Technology discussed the major challenges facing the Australian Government and the food industry:

Managing the risks associated with the presence of food allergens in ingredients and products is a major food safety challenge faced by food manufacturers at all levels of the supply chain.

Companies have a responsibility to manage both the intentional and unintentional presence of allergens in food products and to provide clear and accurate information on their allergen status. These requirements are the same whether the product or ingredients are manufactured or sourced in Australia and New Zealand or are imported.<sup>8</sup>

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<sup>4</sup> Craig Blinco, *Submission 29*, p. 2.

<sup>5</sup> Ms Fiona Cheminant, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 2.

<sup>6</sup> Ms Simone Albert, private capacity, *Committee Hansard*, Melbourne, 18 November 2020, p. 9.

<sup>7</sup> Australian Institute of Food Science and Technology, *Submission 149*, p. 2.

<sup>8</sup> Australian Institute of Food Science and Technology, *Submission 149*, p. 2.

- 4.12 The Australian Food and Grocery Council (AFGC) argued that ‘Food allergen management and labelling in Australia is recognised as the world’s best practice. This results from robust regulatory regimes protecting consumers combined with a voluntary, technically sophisticated, evidence-based, self-regulatory program run by the industry (the Allergen Bureau), for the industry.’<sup>9</sup>
- 4.13 Allergies and Anaphylaxis Australia (A&AA) stated that ‘there is a great need to ensure food importers, ingredient suppliers, manufacturers, regulators, compliance officers and all working in food production understand their responsibilities in food allergen management. Accurate food labelling that is clear and consistent is critical so that consumers with food allergy can make safe and informed decisions about the foods they purchase. Unfortunately food recalls due to undeclared allergens are increasing, with allergen recalls being the reason for the majority of recalls.’<sup>10</sup>

### ***Food Standards Australia New Zealand (FSANZ)***

- 4.14 Food Standards Australia New Zealand (FSANZ) is an independent statutory authority within the Department of Health. It was established under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and operates as an integral part of the food regulation system for Australia and New Zealand.
- 4.15 FSANZ develops and maintains the Australia New Zealand Food Standards Code (the Code). The Code sets out the legal requirements for food produced or imported for sale in Australia and New Zealand.
- 4.16 FSANZ also has other functions in Australia including coordinating food surveillance and food recall systems. It does not however have an enforcement role as food standards in Australia are enforced by the states and territories.

#### *Current standards for food allergy labelling*

- 4.17 FSANZ provided the Committee with the following information on sections of the code that regulate food labelling.
- 4.18 *Standard 1.2.3- Information requirements- warning statements, advisory statements and declarations* of the Code requires the mandatory declaration of the presence of certain foods or substances which can cause severe allergic

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<sup>9</sup> Australian Food and Grocery Council (AFGC), *Submission 127*, p. 3.

<sup>10</sup> A&AA, *Submission 184*, p. 10.

and other reactions in food. The following foods and substances must be declared whenever they are present as ingredients (including when present in food additives and processing aids):

...added sulphites (in amounts of 10 mg/kg or more); cereals containing gluten (namely wheat, barley, rye, oats, spelt and their hybrids), crustacea, egg, fish, milk, peanuts, soybeans, sesame seeds, tree nuts and lupin.<sup>11</sup>

#### 4.19 FSANZ stated:

The declaration must be made on the label of foods for retail sale and foods sold to caterers. For food not in a package or where it is not required to be labelled (for example, food prepared at and sold from a cafe or takeaway), *Standard 1.2.1 - Requirements to have labels or otherwise provide information* requires the declaration of the presence of allergens to either be displayed in connection with the food, or provided to the purchaser on request.<sup>12</sup>

*Standard 1.2.3* also exempts certain highly refined foods and ingredients (e.g. glucose syrup refined from wheat, alcohol distilled from milk whey) from the declaration requirements as these foods were found to be safe for food allergic individuals.<sup>13</sup>

4.20 The Food and Controlled Drugs Branch (FCDB), South Australian Health, commented that allergens are not specifically named in *Standard 3.2.2* of the Code as a risk that food businesses must manage, however it is specified in the labelling standards of Chapter 1 (foods that are required to bear a label, and foods that are required to have labelling information available).<sup>14</sup>

4.21 FCDB suggested that 'Having a dedicated section within Chapter 3 of the Code would mean that there would be no confusion as to the requirement for allergens to be managed by food service businesses and to be assessed during routine inspections.'<sup>15</sup>

#### 4.22 FCDB continued by stating:

Chapter 3 of the Code is planned for review by Food Standards Australia New Zealand (FSANZ), and this presents the perfect opportunity to incorporate allergens specifically as a risk that must be managed by food businesses.

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<sup>11</sup> Food Standards Australia New Zealand (FSANZ), *Submission 173*, p. 3.

<sup>12</sup> FSANZ, *Submission 173*, p. 3.

<sup>13</sup> FSANZ, *Submission 173*, p. 3.

<sup>14</sup> Food and Controlled Drugs Branch (FCDB), *Submission 236*, pp. 2-3.

<sup>15</sup> FCDB, *Submission 236*, pp. 2-3.

Dedicating a clause to allergen management, rather than incorporating it into 'contamination' may give weight to the severity of this issue.<sup>16</sup>

*Plain English Allergen Labelling (PEAL)*

- 4.23 FSANZ told the Committee it is currently working on Proposal P1044 - Plain English Allergen Labelling (PEAL) which would make changes to the Code to make allergen labelling clearer and more consistent. It sought public comment on this proposal through 2019.<sup>17</sup>
- 4.24 FSANZ estimates that the proposed changes would be considered by September 2020, and then the Food Ministers' forum will be notified.<sup>18</sup>
- 4.25 The AFGC was supportive of the work being done by FSANZ in relation to PEAL, noting that the changes:
- ... should result in regulatory changes leading to better allergen labelling of food products which will be clearer, more consistent across food products, and more useful for consumers with allergies in identifying the food products they can eat, and those they must avoid.<sup>19</sup>
- 4.26 FSANZ established the Allergen Collaboration in 2011 with the purpose of strengthening engagement and collaboration amongst key stakeholders in food allergy management with the view to help consumers with a food allergy make safer choices. FSANZ is a member and the Chair of the Allergen Collaboration, as well as providing secretariat support to the group. Members of the Collaboration represent food manufacturing, food service, allergy support groups, health professionals and government.<sup>20</sup>
- 4.27 The Allergen Collaboration maintains an Allergen Portal website which provides links to best practice food allergen resources and key messages that can be promoted in different sectors of the community.<sup>21</sup>
- 4.28 The Allergen Bureau is the peak industry body representing food industry allergen management in Australia and New Zealand. The overall objective

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<sup>16</sup> FCDB, *Submission 236*, pp. 2-3.

<sup>17</sup> FSANZ, *Submission 173*, p. 3.

<sup>18</sup> FSANZ, Mr Mark Booth, Chief Executive Officer, *Committee Hansard*, Canberra, 6 February 2020, p. 1.

<sup>19</sup> AFGC, *Submission 127*, p. 5.

<sup>20</sup> FSANZ, *Submission 173*, p. 3.

<sup>21</sup> FSANZ, *Submission 173*, p. 3.

of the Allergen Bureau is to share information and experience within the food industry on the management of food allergens to ensure consumers receive relevant, consistent and easy to understand information on food allergens.<sup>22</sup>

4.29 The Allergen Bureau informed the Committee about the Global Food Safety Initiative:

In addition to mandatory requirements, food industry may elect to implement food allergy management requirements and recommendations in various industry standards and best-practice guidance resources. The Global Food Safety Initiative (GFSI) is a collaboration between some of the world's leading food safety experts from retail, manufacturing and food service industry, as well as service providers associated with the food supply chain. Food companies that choose to implement a GFSI-recognized scheme do so with the knowledge that they are using an internationally recognized, credible, and comprehensive food safety program. The GFSI mission is to “provide continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide”.<sup>23</sup>

### ***Precautionary Allergen Labelling (PAL)***

4.30 Many submitters raised Precautionary Allergen Labelling (PAL) as an issue that caused a lot of frustration and anxiety. The Committee heard from FSANZ what PAL was used for and how it was regulated.

4.31 FSANZ commented that PAL is used to inform food allergic consumers of the possible presence of food allergens in a product when the allergen was not intentionally added but may have occurred due to cross contact. Food manufacturers may voluntarily use PAL statements (for example, 'May contain ... ') if they are concerned about allergen cross-contact that may have occurred in the supply chain including growing and harvesting of crops, storage and transport of food, or via processing equipment at the manufacturing plant. FSANZ commented:

The Code does not contain any requirements relating to the use of PAL on food labels because there is no agreement in the scientific and medical literature on the allergen threshold for most food allergens. An allergen threshold is usually reported as an allergen intake level (e.g. mg of peanut protein) below which most allergic individuals (except for the most sensitive in the allergic population) will not develop a clinical reaction.

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<sup>22</sup> Allergen Bureau, *Submission 145*, p. 1.

<sup>23</sup> Allergen Bureau, *Submission 145*, p. 7.

Although, the science is still evolving, FSANZ is aware there has been recent progress on determining allergen thresholds for some food allergens, as well as recently commenced work at an international level to achieve consensus on when and how to use PAL. FSANZ is therefore monitoring scientific and regulatory developments internationally, with a view to considering whether future changes to the regulatory arrangements for PAL are needed.<sup>24</sup>

#### 4.32 The AFGC made the following comment on PAL:

Today's supply chains are sophisticated and much is done to maintain the integrity of raw materials (ingredients, additives etc.) as they come down the supply chain and are incorporated into food products. On occasion common equipment for material handling, production lines and facilities is used for the production of different food products resulting in the chance of 'cross contact' and the incidental presence of an allergen at trace levels. One of the more challenging issues for the food processing industry is how best to alert consumers to the possible presence of an allergen in a food product arising from cross-contact during production of the food and this may include the use of a precautionary allergen labelling (PAL) statement. Such statements alert consumers to the possible presence of an allergen by stating the food product may contain the allergen. Alternatively there may be a statement indicating the food was produced in a facility where the allergen was also present. Such statements have been controversial and their use by the food industry criticised on the basis that they restrict consumers choosing foods, when the allergen may not be present at all.<sup>25</sup>

#### 4.33 Dr Zurzolo, Postdoctoral Fellow, Centre for Food and Allergy Research; Melbourne School of Population and Global Health, University of Melbourne, discussed the main issues of food labelling. He commented that PAL presents the biggest problem to consumers due to confusing labelling:

Labelling is a very confusing issue. We have mandatory labelling, which basically covers any ingredient intentionally added to a food product. The food manufacturing industry, I believe, does it quite well. There are some hiccups with plain English, but FSANZ is looking into that and will hopefully provide some recommendations through that.

The biggest issue is what we call precautionary allergy labelling, which is basically providing the statement 'may contain traces' on a food product to alert the consumer that it may or may not have cross-contamination or cross-contact with a food allergen—which may happen during the manufacturing

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<sup>24</sup> FSANZ, *Submission 173*, p. 4.

<sup>25</sup> AFGC, *Submission 127*, p. 6.

process, during shipping or during the cleaning of the manufacturing lines. These statements are voluntary; they are not regulated; they are not standardised by any system at all. And it is the same worldwide, not just here within Australia.

Within a supermarket setting, approximately 65 per cent of processed goods carry a precautionary statement. That makes it incredibly difficult for a food allergic consumer to decide whether a food is actually safe.<sup>26</sup>

- 4.34 Dr Zurzolo commented that his research has found that 'approximately 60 per cent of consumers are ignoring the PAL statements. That is most likely because of how many they are, or because they are becoming complacent with them or because they have eaten them before and they haven't reacted to them. And about 90 per cent of consumers believe the statements are there just to protect the manufacturers from litigation anyway.'<sup>27</sup>
- 4.35 A&AA emphasised that one of the main difficulties caused by PAL is that it is voluntary and unregulated:

Precautionary allergen labels (e.g. 'May contain ...' statements) are voluntary, unregulated and cause confusion for people with food allergy and health professionals. Most products contain a precautionary allergen label without any risk assessment being undertaken and therefore, the information is meaningless.

Other products where there may be real risk, do not contain precautionary allergen labels and the individual is unaware of the risk. Further to this, if an individual with food allergy has an allergic reaction to a packaged food, it is critical that an investigation is undertaken, and the food product removed from the market place if the food is incorrectly labelled.

There is no universal terminology used to communicate cross contamination (when an allergen is unintentionally part of a food product). PAL statements vary widely. Some of the terms used by packaged food manufacturers include 'may contain traces', 'may contain', 'contains traces', 'may be present', 'made in a facility', 'processed on a production line' etc. Consumers wrongly believe each term is related to a level of risk. There remains much confusion in the community around labelling requirements, with a Melbourne study recording

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<sup>26</sup> Dr Giovanni Zurzolo, postdoctoral Fellow, Centre for Food and Allergy Research, Paediatrics Allergist, Murdoch Children's Research Institute and Roya Children's Hospital, *Committee Hansard*, Melbourne, 18 November 2019, p. 26.

<sup>27</sup> Dr Zurzolo, *Committee Hansard*, Melbourne, 18 November 2019, p. 27.

that up to 80% of parents whose children are at-risk of anaphylaxis thought PAL was unhelpful, with many ignoring such statements.<sup>28</sup>

- 4.36 Many inquiry participants gave evidence of their frustration with PAL which often uses ‘may contain traces’ labelling, describing it as unhelpful and too broad.<sup>29</sup>
- 4.37 The Allergen Bureau has developed and provides key best practice allergen management and labelling guidance for the food industry, particularly the globally recognised VITAL® (Voluntary Incidental Trace Allergen Labelling) Program - a standardised allergen risk assessment process for food industry. The VITAL Program is considered a world leading initiative in food allergen management and labelling to ensure consumers receive relevant, consistent and easy to understand information on food allergens.<sup>30</sup>
- 4.38 The NAS suggested the introduction of standardised precautionary allergen labels, such as the Voluntary Incidental Trace Allergen Labelling (VITAL) program:
- Mandate the requirement for food manufacturers to undertake an appropriate risk assessment (e.g. Voluntary Incidental Trace Allergen Labelling (VITAL) to determine whether a product requires a precautionary allergen label and standardisation of the wording used for precautionary allergen labels).<sup>31</sup>
- 4.39 Training in the VITAL Program, developed by the Allergen Bureau, is delivered in Australia and New Zealand and internationally by endorsed Training Providers. A&AA suggested that ‘if the new VITAL symbol IS on pack this will improve confidence in the information on pack whether it has a PAL statement or not.’<sup>32</sup>

### ***Imported foods in Australia***

- 4.40 All imported foods into Australia must comply with the FSANZ Code. This means all imported foods must label the ingredients in English and include allergen labelling.

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<sup>28</sup> A&AA, *Submission 184*, p. 10.

<sup>29</sup> Mrs Suzanne Parry, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 3; Name withheld, *Submission 73*, p. 2; Name withheld, *Submission 161*, p. 3; Mrs Cindy Egan, *Submission 194*, p. 1; Name withheld, *Submission 203*, p. 1; Name withheld, *Submission 107*, p. 2.

<sup>30</sup> Allergen Bureau, *The Vital Program*, < <http://allergenbureau.net/vital/>> accessed 20 March 2020.

<sup>31</sup> NAS, *Submission 118*, p. 7.

<sup>32</sup> A&AA, *Submission 184*, p. 10.

4.41 The Department of Agriculture, Water and the Environment (DAWE) advised the Committee that *Section 34 of the Imported Food Control Act 1992 (IFC Act)* appoints laboratories to conduct food testing under the Imported Food Inspection Scheme (IFIS). To be an appointed analyst, a laboratory must meet stipulated conditions including National Association of Testing Authorities (NATA) accreditation. Accredited laboratories are located within major cities nationally (e.g. Sydney, Melbourne, Brisbane, Adelaide, Perth).<sup>33</sup>

4.42 The Committee was interested to hear if rigorous food testing was carried out on Australian borders in relation to imported foods. DAWE made the following statement:

Food importers are legally responsible for ensuring the foods they import comply with Australian food standards and do not pose a risk to human health. The role of the department under the IFC Act is to monitor the compliance and safety of imported food at the border through the IFIS, a risk based inspection scheme.

All foods referred for inspection under the IFIS are subject to a visual and label assessment. The labelling check includes an assessment of whether mandatory declarations (as required for food allergens) are labelled correctly based on the product's list of ingredients.<sup>34</sup>

4.43 DAWE commented on the process that occurs when imported foods are referred to the IFIS:

Foods referred to IFIS are checked to ensure there is a label printed in English that includes all necessary information (e.g. description of the food, ingredient list, nutrition panel, importer name and address, lot coding and allergen information, as appropriate).

DAWE will test foods where intelligence is available for specific imports, it is not practical or feasible to routinely test imported food for the presence of undeclared allergens to determine whether the food allergen labelling on the product is appropriate.<sup>35</sup>

4.44 DAWE undertakes the following activities to identify and manage the risk of undeclared allergens:

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<sup>33</sup> Department of Agriculture, Water and the Environment (DAWE), *Submission 257*, p.1.

<sup>34</sup> DAWE, *Submission 257*, p.1.

<sup>35</sup> DAWE, *Submission 257*, p.1.

- it monitors international recalls and incidents to identify foods traded internationally that may be non-compliant and whether they are imported into Australia. For example it was recently identified that spring roll wrappers produced in Singapore and recalled in New Zealand and the United Kingdom for undeclared dairy were also imported into Australia. These products were then recalled in Australia and will now be targeted for inspection at the border to ensure future imports include the presence of dairy on the label;
- it implements measures at the border in response to non-compliance identified post border by the state and territory food regulators. For example, imported coconut drinks are tested for the presence of dairy allergens, if not declared on the label, following the report of a death and severe allergic reaction in Australians consuming these drinks in 2015. (see case study below); and
- it responds to alerts received through international food safety networks, including the European Union's Rapid Alert System for Food and Feed (RASFF). Earlier this year RASFF notified Australia that pesto products exported to Australia from Italy contained undeclared peanut due to cross contamination of raw ingredients. Food importers and food regulatory agencies have been working together on this issue to ensure potentially affected product has been recalled and appropriate allergen labelling is now applied.<sup>36</sup>

4.45 The Committee heard that DAWE has 'published an Imported Food Notice on food allergen management to remind importers of the importance of understanding their supply chains to ensure appropriate allergen labelling.'<sup>37</sup>

4.46 The Allergen Bureau highlighted the issue that currently exists with imported foods with the following case study.

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The consequence of an allergic reaction to a food can be tragic – in late 2013, a young boy died after becoming ill after dinner one evening. The child had a known allergy to cow's milk and consumed a coconut drink which was subsequently found to be incorrectly labelled, as the product contained an undeclared cow's milk ingredient.

This tragic death was investigated by the Coroner's Court of Victoria and the

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<sup>36</sup> DAWE, Submission 257, p. 2.

<sup>37</sup> DAWE, Submission 257, p. 2.

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findings handed down in June 2016. The coroner found that:

“On the evidence available to me, I find that [name], who was highly allergic to dairy milk, died after ingesting ‘Brand X Natural Coconut Drink’, a product that has been imported from Taiwan and mislabelled, so as not to declare that it contained dairy.”

There have since been multiple recalls of imported coconut drinks and coconut milk powders that contained undeclared milk in Australia, New Zealand, and throughout the world.

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*Source: Australian Food and Grocery Council, Submission 127, p. 7.*

### ***Drug labelling***

4.47 The Committee received evidence suggesting that a national approach to drug allergy labelling and management is required. Currently medicine labels are being improved however the change is occurring slowly over several years. As allergies are on the rise this issue of drug labelling may become more important as people with allergies require medicines to treat illness.

4.48 The TGA commented that unlike foods most medicines are not required to list all the ingredients on the label:

Some medicines may contain substances that might cause allergic reaction in some people. Unlike foods, most medicines are not required to list all the ingredients that are included in the medicine label. The active ingredient will always be on the medicine label, but only some inactive ingredients, also called excipients, must be on the label. Also, some potential allergens, such as impurities from manufacturing, may not be on the label.<sup>38</sup>

4.49 The Western Australia Child and Adolescent Health Service suggested a national approach was needed to drug allergy management.

We would recommend a national approach to drug allergy management, with increased education about drug allergies, recognition and management of drug allergy and the development of national guidelines for drug allergy confirmation.<sup>39</sup>

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<sup>38</sup> Department of Health, TGA, *Allergies and medicines*, < <https://www.tga.gov.au/allergies-and-medicines>> accessed 20-03-20.

<sup>39</sup> Western Australia Child and Adolescent Health Service, *Submission 182*, p. [3].

4.50 The Western Australian Child and Adolescent Health Services commented that:

Unexpected and adverse drug reactions (ADR) to medicines experienced by consumers may lead them to suspect drug allergy, however, true allergy is uncommon. This is especially relevant for antibiotics of which penicillin is the most commonly reported drug allergy by patients (18 per cent of Australian adult patients and five to seven per cent of children). These patients have increased morbidity and mortality and most are avoiding the medications unnecessarily.<sup>40</sup>

4.51 The Australian and New Zealand Anaesthetic Allergy Group (ANZAAG) commented that there was a great deal of room for improvement for drug labelling:

In a case we know well, the new Aimovig injections, which have provided such a life changing benefit for many living with migraine, were initially not labelled as having a latex component in the injection pen mechanism. This has been corrected, but the product was rolled out globally and significant reactions occurred before the labelling was revised.

In 2010 specialists from fields such as anaesthetists, immunologists, pathologists and allergists, came together to form the Australian and New Zealand Anaesthetic Allergy Group (ANZAAG). Its aim is to foster critical inquiry and research into perioperative anaphylaxis within Australia and New Zealand in order to develop best practice in relation to the prevention, treatment and investigation of perioperative anaphylaxis.<sup>41</sup>

4.52 ANZAAG raised the concern that the number of cases of chlorhexidine anaphylaxis is increasing:

The labelling of chlorhexidine containing products is often poor. Examples of this include the use of small font sizes and the use of the abbreviation CHG, for chlorhexidine, an abbreviation that is not universally recognised. Anaphylaxis to chlorhexidine can result from minimal exposure; such as the use of chlorhexidine containing alcohol wipes to clean intravenous ports prior to drug administration. The use of chlorhexidine containing products has been mandated by numerous health authorities, sometimes with limited evidence of benefit. This includes the requirement to use chlorhexidine containing alcohol wipes to clean intravenous ports prior to drug administration and the short-term use of chlorhexidine coated central venous catheters. The ubiquitous presence of chlorhexidine as a result of the above policies and often

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<sup>40</sup> Western Australia Child and Adolescent Health Service, *Submission 182*, p. [3].

<sup>41</sup> Australian and New Zealand Anaesthetic Allergy Group (ANZAAG), *Submission 116*, p. 1.

inadequate labelling has contributed to the phenomenon of repeated episodes of anaphylaxis to chlorhexidine both before and after a diagnosis of chlorhexidine allergy is made.<sup>42</sup>

## Education and training for allergies and anaphylaxis

- 4.53 The Committee heard that a broad range of education and training was required throughout the health sector to improve the understanding of allergies and recognition of symptoms and appropriate treatment for anaphylaxis. It was told that the Australian community would also benefit from a national allergy and anaphylaxis educational campaign.
- 4.54 Many people reported difficulties in receiving a diagnosis, often having to see several doctors and specialists before their or their child's symptoms could be diagnosed.<sup>43</sup>
- 4.55 This seemed to be a particular problem for sufferers of emerging allergic diseases, such as EoE and FPIES.<sup>44</sup> One inquiry participant reported that it took four years to receive an EoE diagnosis for their child.<sup>45</sup>
- 4.56 Of particular concern was the number of mothers of young children who reported that their concerns about their children were dismissed by medical professionals, these women often being described as 'anxious' or 'overly concerned.'<sup>46</sup>

Because my son was little and he was a first child and for whatever other reason I was considered a very anxious mother. I remember when I finally went to see the gastroenterologist he kind of got angry with me and said, 'Why have you waited so long to bring a child with these symptoms here?' I just

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<sup>42</sup> ANZAAG, *Submission 116*, p. 2.

<sup>43</sup> Ms Carly Morton, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 42; Ms Amanda Lennestaal, *Submission 242*, p. 1; Jana Pearce, *Submission 64*, p. 4; Ms Carolyn Fitzgibbon, *Submission 247*, p. 1; Name withheld, *Submission 26*, p. 1.

<sup>44</sup> Mrs Sarah Gray, President and Founder, ausEE Inc., *Committee Hansard*, Brisbane, 18 February 2020, p. 24; Ms Lennestaal, *Submission 242*, p. 1; Name withheld, *Submission 107*, p. 2. Name withheld, *Submission 226*, p. 3.

<sup>45</sup> Mrs Gray, ausEE Inc., *Committee Hansard*, Brisbane, 18 February 2020, p. 22.

<sup>46</sup> Ms Markeeta Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 1; Mrs Carolina Valerio, private capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 7; Name withheld, *Submission 185*, p. 3.

looked at him. I said, 'Because everyone kept telling me I'm anxious.' He said, 'You are anything but anxious.'<sup>47</sup>

4.57 ASCIA has developed a range of reliable evidence-based allergy and anaphylaxis educational resources for patients, carers, consumers, school staff, early childhood education/care staff, first aid providers and health professionals. These resources include action plans, e-training courses and documents that are accessible online, that can be downloaded and printed. However ASCIA stressed to the Committee that providing, updating and promoting these resources requires ongoing funding.<sup>48</sup>

4.58 The NAS agreed that quality education and training on allergies and anaphylaxis is needed for many health professionals:

Quality education and training for health professionals about allergic diseases and anaphylaxis is often lacking and much needed. With the growing number of young adults with food allergies moving from paediatric to adult care, this will also become an issue for health professionals who manage adult patients.<sup>49</sup>

4.59 The Western Australia Child and Adolescent Health Service agreed that education and training of health professionals is key to improving services to allergy management in Australia:

There is a need to inform patients, the public and all health professionals about allergy and how to recognise and respond to allergic reactions including anaphylaxis. This education and advice needs to be evidence based, up to date, easily accessible and consistent. This will require standardisation of the education and training for all personnel including schools, childcare, first responders and health professionals with regular mandated upskilling as recommended by the Australasian Society of Clinical Immunology and Allergy.<sup>50</sup>

4.60 Professor O'Hehir commented that it is important to improve both doctors' and the general community's awareness of allergies and anaphylaxis:

We have packages such as Up-to-date that most physicians have access to, and under 'Adverse events' it clearly lists certain drugs that may cause angioedema, tongue swelling, cough et cetera. So it comes back to

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<sup>47</sup> ; Mrs Valerio, private capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 7.

<sup>48</sup> ASCIA, *Submission 153*, p. 2.

<sup>49</sup> NAS, *Submission 118*, p. 5.

<sup>50</sup> Western Australia Child and Adolescent Health Service, *Submission 182*, p. 2.

education...But I think it's important that there's community awareness as well as doctor awareness.<sup>51</sup>

- 4.61 The Committee was told that it is difficult to include training in universities when there is only one Professor of Allergy and Immunology in Australia. Professor Douglass described a workforce issue that Australia currently has in relation to allergies and anaphylaxis:

I think the tsunami of allergic disease, which is a First World problem, has caught many First World countries and health systems off guard in terms of workforce capacity. Professor Robyn O'Hehir is the first professor of allergy and immunology in Australia. What teaching do you get in medical schools if you don't have professors who can teach it? Even at that level there is a lack of workforce capacity that's been evident for some time.<sup>52</sup>

### ***Post graduate training for General Practitioners, immunologists and paediatricians***

- 4.62 There is currently a lack of broad-based training in allergic disorders amongst the health workforce at the undergraduate and post graduate level.
- 4.63 ASCIA told the Committee that medical education in relation to allergies and anaphylaxis was inadequate in Australia:

Medical education in the area of allergies and anaphylaxis, both undergraduate and postgraduate, has been inconsistent and inadequate in Australia. This has resulted in the majority of general practitioners, paediatricians, other medical specialists and other health professionals having inadequate training or experience in the management of allergic disease.

This has a flow on effect to patient care, when advice given to patients may be incorrect, inappropriate, inadequate and at times dangerous. Even in 2019, most general paediatrician trainees will qualify with no exposure or training in allergic diseases and will be ill equipped to manage children with allergies.<sup>53</sup>

- 4.64 The Women's and Children's Health Network commented:

There is limited training for those with more general needs such a general practitioners, general paediatricians, child health nurses, and dietitians. This lack of training in what is now a very common health concern, results in

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<sup>51</sup> Professor O'Hehir, *Committee Hansard*, Melbourne, 18 November 2019, p.20.

<sup>52</sup> Professor Douglass, *Committee Hansard*, Melbourne, 18 November 2019, p. 20.

<sup>53</sup> ASCIA, *Submission 153*, p. 2.

misdiagnosis, incorrect and potentially harmful advice, and inappropriate (both failure to under and over refer) referral to specialist allergy care. This in turn increases the burden of illness and cost of care for the consumer/family and community.<sup>54</sup>

4.65 The Western Australia Child and Adolescent Health Service stated that:

...paediatric immunology is highly specialised, with very few paediatric trained specialists in WA. We would advocate for allergy to be included in the curriculum for all Australian Health professional education programs, with a special focus on general practitioners (GPs) and general paediatricians.<sup>55</sup>

4.66 Ms Carly Morton, who lost her husband to bee sting anaphylaxis, commented that there is a poor understanding of anaphylaxis even in the medical field:

In our experience anaphylaxis is often poorly identified and often incompletely managed, including at times in our own institution. Once again, this is related primarily to a lack of education and training. While there are state-based clinical pathways for anaphylaxis management, these appear poorly accessed. Worryingly, many of these episodes go unrecognised and risk being repeated. Furthermore, there is poor documentation of allergen triggers (both food and drugs) within hospital medical records. Because of long waits to see an Allergist, those at risk of anaphylaxis remain so, often without basic emergency plans such provision of an adrenaline auto-injector. State and national KPIs around anaphylaxis management are lacking and a lack of data on this makes planning in this area difficult.<sup>56</sup>

4.67 Dr Hew discussed the limitation in workforce training for allergy specialists in Victoria:

For those close-to-seven-million people, we have two registrar training positions—one at Royal Melbourne and one at the Alfred. It takes about three years to train someone, so that is about one specialist produced a year or sometimes none. I provide specialist services in two specialties— allergy and respiratory medicine. In respiratory medicine, there are 26 training positions in Victoria and one in Tasmania. That is 27. That means nine specialists produced per year, less than one for allergy per year in Victoria. This is a dire state of affairs.

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<sup>54</sup> Women's and Children Health Network, *Submission 255*, p.1.

<sup>55</sup> Western Australia Child and Adolescent Health Service, *Submission 182*, p. 2.

<sup>56</sup> Ms Carly Morton, *Submission 183*, p. 1.

The funding of specialist training in public hospitals depends on the hospital's willingness to fund that position. Again, allergy is predominantly an outpatient specialty. It does not deal with most of the KPIs that individual hospitals are focused on to do with inpatient stay and that therefore makes it difficult for hospitals to initiate training.<sup>57</sup>

- 4.68 The Committee was informed there is one post graduate course available, the Graduate Certificate in Allergy, run out of the University of Western Sydney.<sup>58</sup> In addition there is the Professional Certificate in Allergy Nursing, University of South Australia, catering for those with a special interest in allergy.
- 4.69 The NAS scoping report recommended that allergic diseases be a more significant component of all health professional (including university and where relevant, post graduate) training. This includes collaboration with the Deans of major medical schools and with the Royal Australian College of General Practitioners (RACGP) and Royal Australasian College of Physicians (RACP) to help provide credible education.<sup>59</sup>

### *Allied health professionals*

- 4.70 The Committee received evidence suggesting that allied health care support such as psychologists, counsellors and dieticians have an important role in caring for people with allergies and anaphylaxis. However it was clear that these support areas required specific training for the management of allergies and anaphylaxis.
- 4.71 The Allergy Support Hub commented:
- Dieticians are incredibly valuable in providing daily management and nutritional advice to those with allergies, those with multiple and complex allergic conditions. Psychologists can assist with the social and emotional aspects of managing allergic conditions and help families through challenging times such as food challenges, social isolation, entry to school, subsequent children, childhood anxiety, food avoidance/fear and assist the psychological impact for adults with severe allergic condition.<sup>60</sup>

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<sup>57</sup> Dr Hew, *Committee Hansard*, Melbourne, 18 November 2019, p. 16.

<sup>58</sup> APS, *Submission 84*, p. 1.

<sup>59</sup> NAS, *Submission 118*, p. 5.

<sup>60</sup> Allergy Support Hub, *Submission 109*, p. 3.

- 4.72 Dietitians are often at the forefront of nutritional management of non-IgE-mediated food allergies such as food protein induced proctocolitis and food protein induced enteropathy, which in many cases requires manipulation of the maternal diet during breastfeeding. A thorough understanding of the nutritional requirements of breastfeeding, appropriate food substitution, and when and how to reintroduce allergens to the maternal and/or infant diet is required.<sup>61</sup>
- 4.73 Dr Merryn Netting told the Committee that ‘currently basic undergraduate training for dietitians includes limited information regarding food allergy management. In addition, dietitians working in food service management require specialist training in allergen handling.’<sup>62</sup>
- 4.74 To address this knowledge gap, ASCIA offers free online e-training in food allergy. However this does not make a dietitian competent in allergy management. ASCIA commented:

We have sought to address this need by development of a two-day, evidence based, peer reviewed face to face ASCIA training course in association with the Dietitians Association of Australia Centre for Advanced Learning, however this course comes at a cost to the individual which limits its accessibility.<sup>63</sup>

### ***Vocational Education Training - Hospitality***

- 4.75 The Committee received evidence advocating for improved practices in hospitality and training in relation to allergies.<sup>64</sup>
- 4.76 The NAS advocated for accredited food allergy training to be incorporated in hospitality courses. The NAS called for the ‘inclusion of an accredited food allergen management training course that meets the National Allergy Strategy Minimum standards for food allergen management training, in all hospitality training courses.’<sup>65</sup>
- 4.77 The Allergen Bureau told the Committee that they believe a gap currently exists in the institutional education for food manufacturing professionals:

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<sup>61</sup> Dr Merryn Netting, *Submission 222*, p. 2.

<sup>62</sup> Dr Merryn Netting, *Submission 222*, p. 2.

<sup>63</sup> Dr Netting, *Submission 222*, p. 2.

<sup>64</sup> Andrea Dawson, *Submission 1*, p. 1; M post, *Submission 39*, p. 1.

<sup>65</sup> NAS, *Submission 118*, p. 14.

Many of the current TAFE and University courses, for general manufacturing workers through to food science graduates, do not adequately address food allergens and their management. To address this gap, a review of the Cert I, II and III in Food Processing is currently underway, led by Skills Impact, and subject matter experts in food allergen management have been consulted in this area.

Food science degrees in university also do not all address food allergens and their management in food industry – being knowledge which is traditionally obtained once working in the industry.<sup>66</sup>

- 4.78 Several submitters suggested a certificate to serve food safely with regard to allergies, similar to the Responsible Service of Alcohol (RSA) certificate:

Given the increasing prevalence of anaphylaxis and the risk to life if hospitality staff inadvertently serve a person food containing that person's allergen, I would like to see a mandatory 'Allergies and Anaphylaxis' training program that servers of food are required to undertake, similar to how servers of alcohol are required to undertake a 'Responsible Service of Alcohol' program.<sup>67</sup>

- 4.79 In relation to education and training, the Restaurant and Catering Industry Association (R&CA) suggested that allergen and anaphylaxis training be incorporated into food safety and handling training nationwide:

Currently, there are three levels of training available to employees within food businesses, a safe food handling certificate (both back and front of house) which is issued by state food regulation agencies as well as a single food safety supervisor who is responsible for management of food safety practices across the business. Also, a single staff member (usually the front of house restaurant manager) will hold a full first aid certificate. The food safety supervisor may have some allergen training, but this is an optional competency in certain states and not common across food service businesses.<sup>68</sup>

- 4.80 R&CA has long held the view that mandating training for food handlers under a nationally consistent system is good public policy.<sup>69</sup>

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<sup>66</sup> Allergen Bureau, *Submission 145*, p. 8.

<sup>67</sup> Andrea Malhotra, *Submission 34*, p. 2; NAS, *Submission 118*, p. 6; Maurice Blackburn, *Submission 141*, p. 5.

<sup>68</sup> Restaurant and Catering Industry Association, *Submission 229*, p. 2.

<sup>69</sup> Restaurant and Catering Industry Association, *Submission 229*, p. 2.

- 4.81 Currently in Australia only NSW, ACT, QLD and VIC require businesses to have a food safety supervisor. In the jurisdictions where a food safety supervisor is required, there are differences with regards to:
- Which businesses are required to have a food safety supervisor and the reasoning behind why they need to have a food safety supervisor;
  - The training requirements for food safety supervisors;
  - Whether a period of currency applies to the training required; and
  - Regulation of training provided to food safety supervisors.<sup>70</sup>
- 4.82 NSW is the only jurisdiction that regulates the training for food safety supervisors and NSW has included food allergen management in this training.<sup>71</sup>
- 4.83 The Committee received a submission from the Food and Controlled Drugs Branch, South Australian Health that suggested that food service businesses who choose to offer allergen free foods may be required to have a dedicated ‘allergen free zone’ or a separate equipment and utensils or thorough cleaning process before preparing allergen free food.<sup>72</sup>

### *Schools*

- 4.84 The management of schools is a state and territory issue. However the Committee received significant evidence from individuals regarding the inconsistent management practices of allergies and anaphylaxis across many Australian schools.
- 4.85 Inquiry participants reported mixed experiences with their children in schools. Several witnesses noted that each state and territory has different guidelines for the management of allergies within schools. In addition there seems to be a great deal of variance between schools as to how well these guidelines are followed.<sup>73</sup>
- 4.86 Some parents reported working with their schools to develop management plans for their child’s circumstances and being disappointed to find out after

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<sup>70</sup> NAS, *Submission 184*, p. 13.

<sup>71</sup> NAS, *Submission 184*, p. 13.

<sup>72</sup> Food and Controlled Drugs Branch, South Australian Health, *Submission 236*, p. 2.

<sup>73</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 2; Name withheld, *Submission 136*, p. 1; Name withheld, *Submission 185*, p. 2; Name withheld, *Submission 107*, p. 3; Name withheld, *Submission 52*, p. 2; Name withheld, *Submission 227*, p. 3.

reactions or anaphylactic episodes that these guidelines were ignored.<sup>74</sup> As an example, one parent wrote about their child being sent to the toilet alone after a reaction which was directly against their allergy management plan.<sup>75</sup>

- 4.87 Other people reported gaps in care for children with allergies, such as children being served food with allergens during school camps.<sup>76</sup>
- 4.88 Many parents reported feeling like they are troublesome and a burden to the school.<sup>77</sup> Others reported being rejected from schools because of their child's severe allergies.<sup>78</sup>
- 4.89 Many parents of children with allergies reported bullying of their children at school,<sup>79</sup> as well as children being excluded from activities or food-based rewards or special events.<sup>80</sup>
- 4.90 In terms of education and training for schools the Committee was impressed with the evidence received from the NSW Anaphylaxis Education Program (NSWAEP). This program:

... is unique in both NSW and Australia and was established in 2004 to improve and support state wide anaphylaxis education in response to the growing need in the community and in response to the death of Hamidur Rahman on a high school camp in NSW in 2002.

In 2017-2018, it has enabled the training of over 120 000 school staff across the Department of Education in schools in NSW. The purpose of the NSWAEP is

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<sup>74</sup> Name withheld, *Submission 181*, pp. 1-2; Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, pp. 3-4; Name withheld, *Submission 95*, p. 2.

<sup>75</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, pp. 3-4.

<sup>76</sup> Ms Cheminant, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 5; Name withheld, *Submission 98*, p. 2; Mandy and Francis Hogan, *Submission 250*, p. 5.

<sup>77</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 2; Mrs Monique Boatwright, *Submission 195*, p. 3; Mandy and Francis Hogan, *Submission 250*, p. 3; Jo-anne Hickey, *Submission 65*, p. 3.

<sup>78</sup> Ms Culley, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, pp. 3-4.

<sup>79</sup> Ms Cheminant, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 1; Ms Bella Gray, member, ausEE Inc., *Committee Hansard*, Brisbane, 18 February 2020, p. 24; Mrs Boatwright, *Submission 195*, p. 3; Name withheld, *Submission 131*, p. 5; Name withheld, *Submission 171*, p. 1; Name withheld, *Submission 202*, p. 2; Miss Courtney Ward, *Submission 198*, p. 3.

<sup>80</sup> Mandy and Francis Hogan, *Submission 250*, pp. 3-4; Mr Glen Turnbull, *Submission 106*, p. 1; Name withheld, *Submission 131*, p. 5; Name withheld, *Submission 27*, p. 1; Name withheld, *Submission 77*, p. 1.

to disseminate high quality, evidence-based training and to educate individuals and groups in the recognition and management of anaphylaxis with a particular focus on schools.<sup>81</sup>

4.91 NSWAEP works closely with ASCIA to develop school programs for anaphylaxis:

The NSWAEP is recognised as the peak training body for recognition and management of anaphylaxis for the school and children’s service sectors across NSW. The specialist allergy nurses who work for the NSWAEP all hold post graduate qualifications in Allergy Nursing and are active members of ASCIA.<sup>82</sup>

### ***First aid training***

4.92 Several submitters called for the inclusion of allergies and anaphylaxis training in all first aid courses delivered across Australia.<sup>83</sup> Including an allergies module in first aid training would gradually increase the understanding and awareness of allergies and anaphylaxis within the broader community in Australia.

4.93 Dr Michelle Warton suggested that like training for defibrillators, adrenaline auto-injectors could also be included in first aid training.<sup>84</sup>

4.94 Asthma Australia noted that there was a need to incorporate anaphylaxis first aid training into various settings.<sup>85</sup>

### **Food service**

4.95 The food service industry workforce has a high turnover of staff that receives little to no training in some cases. Several witnesses made suggestions on possible improvements to systems and training of staff in the food service sector.

4.96 The NAS commented that allergic reactions to food purchased from the food service sector remains an issue for people with food allergy. Severe allergic reactions, including fatalities, continue to occur.<sup>86</sup>

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<sup>81</sup> NSW Anaphylaxis Education Program (NSWAEP), *Submission 126*, p. 1.

<sup>82</sup> NSWAEP, *Submission 126*, p. 1.

<sup>83</sup> Ms Elizabeth Boyle, *Submission 225*, p. 2.

<sup>84</sup> Dr Michelle Warton, *Submission 224*, p. 2.

<sup>85</sup> Asthma Australia, *Submission 230*, p. 4.

<sup>86</sup> NAS, *Submission 118*, p. 6.

4.97 The NAS suggested prompt and standardised investigations should be carried out in response to reported food allergy reactions in food service:

Prompt environmental health officer investigation of food service premises using standardised protocols in response to a reported food allergic reaction in food service. Where deaths have occurred, the investigation is carried out by the environmental health officer alongside police.<sup>87</sup>

4.98 Mr Newling of Maurice Blackburn Lawyers, commented on the lack of education and training available to staff working in the hospitality industry. He stated:

Where the system seems to fall down seems to be the line of communication between kitchen staff and wait staff. We're concerned that education and training on the double-checking mechanisms that would make it impossible for the wrong plate to be served to the wrong person may be missing. This is just as relevant in restaurants as it is in hospitals, childcare facilities, aged-care homes...<sup>88</sup>

4.99 Maurice Blackburn Lawyers suggested that:

...all food service providers must have a system or policy in place to ensure that the right person gets the right meal. There should be a requirement that the existence of such a system or policy is compulsory and therefore should be reinforced by regular inspections and audits; that there are documented consequences for breaching that requirement; and that the curriculum of relevant certificate courses reflects such workplace systems or policies that must be in place and adhered to.<sup>89</sup>

4.100 Many people with severe allergies reported not eating out or doing so rarely due to safety concerns.<sup>90</sup> Some of these people reported being turned away from restaurants<sup>91</sup> or being told to eat outside when they attempted to bring their own food from home for a child with severe allergies.<sup>92</sup>

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<sup>87</sup> NAS, *Submission 184*, p. 6.

<sup>88</sup> Mr Peter Newling, National Manager, Public Policy, Maurice Blackburn Lawyers, *Committee Hansard*, Melbourne, 18 November 2019, p. 37.

<sup>89</sup> Mr Newling, *Committee Hansard*, Melbourne, 18 November 2019, p. 37.

<sup>90</sup> Name withheld, *Submission 1*, p. 1; Name withheld, *Submission 21*, p. 1; Name withheld, *Submission 165*, pp. 2-3; Mr James Norton, *Submission 144*, p. 1; Name withheld, *Submission 99*, p. 2.

<sup>91</sup> Ms Eloise Roelandts, private capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 9; Miss Nelson, *Submission 16*, p. 2; Name withheld, *Submission 107*, p. 2; Mrs Vicki Nikolovska-Wright, *Submission 211*, p. 1.

<sup>92</sup> Mrs Sarah Dubravica, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, pp. 5-6.

- 4.101 Inquiry participants reported that in general food servers and kitchen staff had little training or understanding of allergies.<sup>93</sup>
- 4.102 Despite these issues, the inquiry did receive some reports of restaurants expending extra effort to ensure the safety of patrons with allergies.<sup>94</sup>
- 4.103 Numerous inquiry participants highlighted their frustration with speciality food stores such as bakeries or butchers not listing ingredients for their products and employees being unable to advise what allergens were in the food they were selling.<sup>95</sup>

#### *Airlines*

- 4.104 The Committee received evidence from people with allergies and anaphylaxis who had difficulties flying on airline carriers both within Australia and overseas due to their food allergies.
- 4.105 Dr Hew discussed public policy relating to airlines and their policies for food allergy. He informed the Committee that A&AA surveyed 33 airlines to find out what their general policies were with regard to food allergies:

Of 33 Airlines, 40 per cent did not have information available on their website and 40 per cent had no availability of information by telephone contact. If you put that together, 20 per cent had no information available by either telephone contact or by website at that time.

Only one of 33 airlines was willing to say that they had an adrenaline supply in the emergency boxes on every flight. That means 32 out of 33 airlines either did not or were not willing to commit to that. We would suggest that this is really important.<sup>96</sup>

- 4.106 Dr Hew advocated for airlines to carry adrenaline auto-injectors as he said it is possible that some passengers may develop anaphylaxis for the first time in the air:

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<sup>93</sup> Miss Byers, *Submission 3*, p. 2; Name withheld, *Submission 43*, p. 2; Ms Murtagh, *Submission 89*, p. 1; Name withheld, *Submission 210*, p. 1; Name withheld, *Submission 42*, p. 2; Mr Stephen and Rebecca Roberts, *Submission 147*, p. 1.

<sup>94</sup> Ms Roelandts, private capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 10.

<sup>95</sup> Miss Juliana Byers, *Submission 3*, p. 1; Name withheld, *Submission 136*, p. 2; Name withheld, *Submission 165*, p. 2; Name withheld, *Submission 95*, p. 1; Name withheld, *Submission 22*, p. 4; Name withheld, *Submission 2*, p. 1.

<sup>96</sup> Dr Hew, *Committee Hansard*, Melbourne, 18 November 2019, p. 18.

Passengers are, in general, responsible for their own medical management but if you forget to bring the adrenaline injectors, or the adrenaline injector is insufficient to treat the anaphylaxis event, or individuals may develop anaphylaxis for the first time in the air. It is possible to die from anaphylaxis in less time than it takes to land an airplane.<sup>97</sup>

4.107 One submitter commented that ‘some international airlines offer ‘nut exclusion zones’ which are safe for families with kids with allergies to sit. In addition, some airports in international destinations have adrenaline auto-injectors on display on walls next to defibrillators.<sup>98</sup>

4.108 Another submitter told the Committee that she had difficulties taking her own allergen free food on an international flight:

On both of my experiences in travelling overseas, I have had immense trouble with security letting ice packs onto the plane so that my food can remain cold. As I cannot eat any of the airline provided meals because of allergy, I must take my own food for the duration of the flight. When going through security, officials are extremely persistent that ice is only allowed onto the plane for individuals traveling with baby formula/breast milk and medication. My medical needs that therefore require me to take my own food are apparently not satisfactory despite the fact that I provide up to date doctors’ letters explaining my situation. This was sustained by multiple levels of supervisors.

On the most recent trip (December 2018/January 2019) the only reason ice packs for my food were allowed onto the plane was because my mum had, at the last minute decided to throw in some probiotics. The probiotics were considered ‘medication’ and so ice packs were allowed to keep the bottle cold. These experiences have caused me much anxiety and distress in a situation (overseas travel) that is already uncomfortable and anxiety provoking for many. I do not think that border security protocol is inclusive of those who have allergy.<sup>99</sup>

### *Hospitals*

4.109 The Committee recognises that hospitals fall under the direction of states and territories. However the Committee received evidence about the lack of assistance when patients with severe food allergies were admitted to hospital throughout Australia.

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<sup>97</sup> Dr Hew, *Committee Hansard*, Melbourne, 18 November 2019, p. 18.

<sup>98</sup> Name withheld, *Submission 27*, p. 1.

<sup>99</sup> Name withheld, *Submission 51*, p. 4.

- 4.110 There were many reports of very poor food service in hospitals for people with allergies. Many people reported being served food with allergens in it despite informing the hospital before admission of food allergies.<sup>100</sup>
- 4.111 Others reported hospitals being unable to provide them with allergen free food, or being offered incomplete meals such as a banana for an adult man's dinner.<sup>101</sup>
- 4.112 Many parents of children with food allergies stated that after several days of being served food with allergens in it, they started bringing pre-made food into the hospital for their child to eat. This was an added stress to an already stressful time.<sup>102</sup>
- 4.113 Mr Simon Tate and Ms Gabrielle Catan's son Louis died in hospital in 2015. He was admitted to hospital for an asthma attack. During Louis' time in hospital, his parents commented on the lack of food and safety policies within the hospital. Being fed food in hospital which contained allergens led to Lewis' death:

Louis died on the 23rd of October 2015. Louis was admitted to Frankston Hospital, Victoria, for an asthma attack. On admission the hospital were notified of his food allergies and the fact that he carried an EpiPen. Louis was served a hospital breakfast that resulted in anaphylaxis and died due to the severity of the anaphylaxis and a subsequent reaction to general anaesthetics.

Our experience has been that there are no consistent food safety policies and procedures in hospitals across Australia in respect to food allergens. Hospitals seem to develop their own protocols, with different interpretation of the Food Safety Act and industry practice.<sup>103</sup>

- 4.114 Mr Tate and Ms Catan recommended that:

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<sup>100</sup> Ms Murtagh, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 3; Name withheld, *Submission 48*, p. 3; Miss Ashley Wong, *Submission 51*, p. 2; Name withheld, *Submission 27*, p. 3; Name withheld, *Submission 52*, pp. 2-3; Name withheld, *Submission 119*, p. 2; Ms Murtagh, *Submission 89*, pp. 1-2.

<sup>101</sup> Mr Nathan Pokoney, *Submission 104*, p. 7; Mrs Pokoney, *Submission 135*, p. 6; Name withheld, *Submission 185*, p. 4; Name withheld, *Submission 95*, p. 2.

<sup>102</sup> Ms Cheminant, private capacity, *Committee Hansard*, Adelaide, 17 February 2020, p. 5; Mrs Karen Wong, *Submission 7*, p. 2; Miss Wong, *Submission 51*, p. 2; Name withheld, *Submission 12*, p. 4; Name withheld, *Submission 77*, p. 3; Name withheld, *Submission 165*, p. 3; Name withheld, *Submission 52*, p. 2; Name withheld, *Submission 202*, p. 1; Name withheld, *Submission 57*, pp. 1-2.

<sup>103</sup> Simon Tate and Gabrielle Catan, *Submission 72*, p. 1.

...there should be a National Safety and Quality Health Service (NSQHS) standard set by the Australian Commission on Safety and Quality in Health Care in respect to food safety for patients with food allergies. Food safety is currently not seen as a clinical matter in hospital and as such there is an apparent lack of ownership and accountability across the healthcare sector and various government departments.<sup>104</sup>

- 4.115 The NSWAEAP commented on hospital incident reporting showing evidence of how easily children can be fed foods they are allergic to while they are in hospital. It found that screening and documentation of food allergies was inconsistent within the hospital setting, with staff reporting that allergy documentation tools are confusing and misused.<sup>105</sup>
- 4.116 Confusion in relation to access and use of adrenaline auto-injectors (EpiPen) is another concern. NSWAEAP pointed out that 'EpiPens are often not brought to hospital by families, however when they are, hospital staff have no clear guidelines about their roles and responsibilities and the prescribing of EpiPens on inpatient medical charts.'<sup>106</sup>
- 4.117 Asthma Australia advised the Committee that its consumer feedback included instances where patients were not permitted to take their EpiPen with them during hospital admission, highlighting the need for greater education for consumers and health practitioners in a range of settings.<sup>107</sup>
- 4.118 The NAS has developed a resource for food allergen management in hospitals.<sup>108</sup> Developed in conjunction with Queensland Health, this resource includes best practice guidelines, policy and audit tool templates, and an ingredient substitution tool. The guide also includes a menu assessment tool which was developed with the Dietitians Association of Australia. It is freely available for use on the NAS website.<sup>109</sup>

## Committee comment

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<sup>104</sup> Simon Tate and Gabrielle Catan, *Submission 72*, p. 1.

<sup>105</sup> NSWAEAP, *Submission 126*, p. 4.

<sup>106</sup> NSWAEAP, *Submission 126*, p. 4.

<sup>107</sup> Asthma Australia, *Submission 230*, p. 5.

<sup>108</sup> NAS, *Submission 118*, p. 6.

<sup>109</sup> NAS, *Food Service in Healthcare* <<https://nationalallergystrategy.org.au/resources/food-service-healthcare>> viewed 20 March 2020.

- 4.119 Food labelling was an issue that received significant attention throughout the inquiry. The Committee was moved by some of the accounts from individuals and families during the inquiry, about how difficult daily routines become when a person has a food allergy, let alone multiple food allergies. The Committee appreciates that our society places a great deal of importance on food sharing for socialising and celebrating many occasions. Therefore the Committee understood the difficulties and confusion people with allergies faced when scrutinising food product labels in supermarkets and food outlets.
- 4.120 The Committee believes that food labelling requires urgent attention in the areas of Plain English Allergen Labelling (PEAL) and Precautionary Allergen Labelling (PAL). Food Standards Australia New Zealand (FSANZ) should work to implement changes to PEAL before September 2020.
- 4.121 The Committee recommends that the Allergen Bureau continues to work closely with the food industry to consistently use the VITAL program for relevant food products and to develop a label to demonstrate that a product has been assessed.
- 4.122 It was evident that there was an urgent need to educate and upskill many health professionals in order to obtain optimal management of allergic disease in Australia. In addition to the medical profession, the Committee recognised there was a great need to educate the general community and other important industries such as food service, schools, hospitals and airline industries in allergies and anaphylaxis.
- 4.123 The inclusion of an allergies and anaphylaxis module in first aid training is a practical solution to improve knowledge and understanding across the community. The Committee supports the need for a national standardised first aid course that includes allergy and anaphylaxis training.
- 4.124 My Health Record will greatly assist the health care sector to understand the high prevalence rates of allergies. The Committee supports all policy measures that increase the confidence in and uptake of the use of the electronic My Health Record. The Committee notes the importance of individuals keeping their My Health Record up to date. Increasing the uptake of MHR will assist all medical specialists and pharmacists to understand and treat drug allergy and food allergies with more consistency.
- 4.125 The food service industry requires education and training in allergy and anaphylaxis management. Allergy training should be incorporated into training modules within the vocational education training sector. The Committee recognises the food service industry has a fluid workforce with

people coming in and out of the casual workforce regularly. However, the Committee believes that those undertaking training in hospitality and food service should receive at least some education and training on food allergies and anaphylaxis.

- 4.126 Environmental health officers that attend investigations for allergen contamination in the food service industry should be trained in allergy and anaphylaxis education, in order for them to have a better understanding of sensitivities and contamination risks for people with allergies. The Committee believes that an increased awareness and understanding of allergies throughout the food sector industry and the Australian community will be beneficial for everyone living with allergies and anaphylaxis.
- 4.127 Hospitals are an issue for all states and territories, however the Committee urges all hospitals to reconsider funding arrangements for allergy and immunology specialist placements, including allergy nurses and specialist doctor placements, in order to alleviate long waiting lists in public hospitals. The Committee also encourages hospitals to consider implementation of the resource for food allergen management in hospitals developed by the National Allergy Strategy.
- 4.128 The Committee encourages all airlines to improve the safety of passengers with allergies and in particular, those passengers who are living with anaphylaxis. Australian airlines should give consideration as to how it can provide food to passengers with allergies or have a policy that allows for passengers to carry adequate food for themselves on international flights.
- 4.129 The Committee believes all seats of travellers who have emergency care plans for anaphylaxis should be wiped down before boarding; cabin crew should receive first aid training that includes anaphylaxis training, recognising symptoms of anaphylaxis and an understanding of how to administer an adrenaline auto-injector; and all airlines be required to carry at least two adrenaline auto-injectors in first aid kits on domestic and international flights entering and departing Australia.

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## **Recommendation 14**

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- 4.130 The Committee recommends that the Australian Government review all work, health and safety standards within vocational education training to ensure all food service and food preparation training modules include training on allergies and anaphylaxis, including the prevention of food cross contact.**

### **Recommendation 15**

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**4.131** The Committee recommends that the Allergen Bureau in collaboration with Food Standards Australia New Zealand (FSANZ), work with the food industry to encourage the consistent use of the VITAL food allergen risk assessment program, including the introduction of a VITAL 'V' tick on packaging to inform consumers that a product has been through this process.

### **Recommendation 16**

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**4.132** The Committee recommends that the Australian Government work with state and territories to mandate allergen regulations for all hospitals, to ensure that allergen free meals are made available to all patients.

### **Recommendation 17**

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**4.133** The Committee recommends that Food Standards Australia New Zealand (FSANZ) expedites the finalisation of the Plain English Allergy Labelling (PEAL) process before September 2020 and informs the Committee once the process has been finalised.

### **Recommendation 18**

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**4.134** The Committee recommends that Food Standards Australia New Zealand (FSANZ) prioritises work in relation to reformulation labels on products. Any product that has changed its ingredients should have either new packaging alerting consumers to the reformulation, or should have a sticker placed on the front stating clearly that new ingredients have been added.

### **Recommendation 19**

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**4.135** The Committee recommends that all staff at Australian primary and secondary schools receive nationally consistent education and training for recognising and responding to anaphylaxis.

### **Recommendation 20**

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**4.136** The Committee recommends that the Department of Health work with the Australasian Society of Clinical Immunology and Allergy (ASCIA) and all states and territories to ensure that treatment for anaphylaxis be

**incorporated into a nationally standardised first aid training course, and if necessary to provide additional funding to first aid training providers to facilitate this.**

## **Recommendation 21**

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**4.137 The Committee recommends that the Australian Government work with the Australasian Society of Clinical Immunology and Allergy (ASCIA) and state and territories to include information about allergies and anaphylaxis education and training into undergraduate teacher training degrees, learning support assistant training and childcare worker vocational education training.**

## **Recommendation 22**

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**4.138 The Committee recommends that the Australian Government requires that all airlines in and out of Australia undertake the following to assist with customers requiring anaphylaxis care:**

- seats of travellers who have emergency care plans for anaphylaxis should be wiped down before boarding;**
- cabin crew should receive first aid training that includes anaphylaxis training, recognising symptoms of anaphylaxis and an understanding of how to administer an adrenaline auto-injector; and**
- require all first aid kits on domestic and international flights entering and departing Australia to carry at least two adrenaline auto-injectors.**



# 5. Research and emerging treatments

## Overview

- 5.1 There is limited research and funding for allergies and anaphylaxis in Australia. However the current research is of critical importance as it has already begun research studies that are looking for a better understanding of why allergies are on the rise. Importantly, Australian researchers are sharing some information with international researchers in the study of allergies and anaphylaxis.
- 5.2 This chapter outlines research currently being undertaken in Australia relating to allergies and immunology as well as research partnerships with other countries. The current status of oral immunotherapy for allergies both in Australia and overseas is discussed, as well as new medications and alternative therapies.

## Research in Australia

- 5.3 Research into allergy includes not just the search for a cure or harm minimisation for allergy sufferers but the research into the causes of allergies and the cause of the sharp rise in childhood allergies which has occurred in the last twenty years.
- 5.4 The Australian Society of Clinical Immunology and Allergy (ASCIA) stated that there is a strong need to increase the understanding of the underlying causes of allergic disease, as this will lead to improved treatments.<sup>1</sup>

## *Research funding*

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<sup>1</sup> Australasian Society of Clinical Immunology and Allergy (ASCIA), *Submission 153*, p. 4.

- 5.5 The Department of Health is committed to health and medical research and has several funding models which provide opportunities for research into both risk factors and treatments for allergies.<sup>2</sup>
- 5.6 The Department of Health's Medical Research Future Fund (MRFF) is an endowment fund to provide sustainable funding for medical research in the medium and longer term. It has provided \$437,000 to the University of Western Australia for a research project into what dietary factors increase the risk for children developing food allergies.<sup>3</sup>
- 5.7 Professor Brandon Murphy, the Chief Medical Officer of the Department of Health, said that one of the core areas of the MRFF is translational research and clinical trials.<sup>4</sup>
- 5.8 The Biomedical Translation Fund (BTF) is a for-profit venture capital fund which matches funding to Australian biomedical start-ups that have secured private capital investment. So far, it has invested in two companies focused on allergies and anaphylaxis:
- ProTA Therapeutics Pty Ltd has received \$10 million for development of a new treatment into food allergies in children and adults; and
  - Aravax Pty Ltd has received \$5.59 million for research into a new type of peptide immunotherapy to treat peanut allergy.<sup>5</sup>
- 5.9 The National Health and Medical Research Council (NHMRC) have also provided a grant of \$6 million to the Murdoch Children's Research Institute (MCRI) for food allergy research.<sup>6</sup>
- 5.10 Ms Carolina Valerio, a clinical research nurse at the Children's Hospital at Westmead, noted in her submission that no allergy specific research received a grant from the NHMRC in the most recent round of funding. The Children's Hospital at Westmead had previously received a grant to undertake research into oral immunotherapy. Due to a lack of funding, this

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<sup>2</sup> Dr Lisa Studdert, Deputy Secretary, Department of Health (DoH), *Committee Hansard*, Canberra, 24 October 2019, p. 1.

<sup>3</sup> Department of Health (DoH), *Submission 78*, p. 11.

<sup>4</sup> Prof Brendan Murphy, Chief Medical Officer, Department of Health (DoH), *Committee Hansard*, Canberra, 24 October 2019, p. 3.

<sup>5</sup> DoH, *Submission 78*, p. 11.

<sup>6</sup> Dr Studdert, DoH, *Committee Hansard*, Canberra, 24 October 2019, p. 4.

hospital's Chair of Allergy and Clinical Immunology position is vacant and cannot be filled.<sup>7</sup>

- 5.11 Ms Valerio also said private funding from charities is highly competitive and the amounts awarded are often insufficient to fund complete research studies. She has undertaken the task of fundraising for her department and describes it as 'an additional full time, unpaid job'.<sup>8</sup>
- 5.12 Dr Melanie Wong, at the Children's Hospital at Westmead, stated there is active research into allergies being undertaken in Victoria, Western Australia, New South Wales and South Australia. All of these research groups require support and funding in order to translate their findings into clinical practice.<sup>9</sup>
- 5.13 One of the leading research facilities in Australia in the area of food allergy research is the Centre for Food Allergy Research (CFAR). CFAR was established in 2013 as a collaboration of researchers and clinicians in Australia, funded by the NHMRC. It is currently supported by a NHMRC Centre of Research Excellence (CRE) grant which will expire in 2022.<sup>10</sup>
- 5.14 Dr Catherine Hornung of CFAR stated that most of CFAR's individual trials are funded through grants and CFAR provides funding for some of its PhD and postdoctoral researchers.<sup>11</sup>
- 5.15 Dr Hornung went on to say that CFAR would like more funding to employ experts in health economics and implementation evaluation experts in order to ensure the outcomes of their research are able to be implemented effectively at a policy level.<sup>12</sup>
- 5.16 Without funding for CFAR, the framework that it provides for research collaboration would be lost, as well as the ability of researchers to speak to other leading medical experts and allergy patient advocacy organisations, such as ASCIA and Allergy and Anaphylaxis Australia (A&AA).

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<sup>7</sup> Mrs Carolina Valerio, *Submission 154*, p. 3.

<sup>8</sup> Mrs Valerio, *Submission 154*, p. 3.

<sup>9</sup> Dr Melanie Wong, Senior Staff Specialist and Head, Department of Allergy and Immunology, The Children's Hospital at Westmead, *Committee Hansard*, Sydney, 19 November 2019, p. 23.

<sup>10</sup> Centre for Food & Allergy Research (CFAR), *Submission 97*, p. 1.

<sup>11</sup> Dr Catherine Hornung, Coordinator, Centre for Food Allergy Research (CFAR), *Committee Hansard*, Melbourne, 18 November 2019, p. 24.

<sup>12</sup> Dr Hornung, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 24.

- 5.17 Dr Hornung stated ‘we feel very strongly that we need to continue to have that framework to pull all the researchers together so that there is one body to look to for this kind of expertise.’<sup>13</sup>
- 5.18 Since 2015, ausEE Inc., a patient support and advocacy organisation for sufferers of Eosinophilic Gastrointestinal Disorder (EGID), has contributed almost \$100,000 to research into the treatment and diagnosis of EGID. They note this is a relatively small amount raised from donations from supporters and would like the MRFF to prioritise more research into EGID in the future.<sup>14</sup>
- 5.19 The Australian College of Nursing (ACN) stated there has not been a significant increase in allergy research funding since 2015. It said ‘there is a need for a great deal more research funding to identify the multifaceted underlying causes of allergy and anaphylaxis so that consistent, evidence-based management and treatment strategies can be developed.’<sup>15</sup>
- 5.20 In one submission, the author stated they would like to see a balance of funding for research into prevention of further allergies and treatments for current allergy sufferers.<sup>16</sup>

### *Current trials*

- 5.21 Currently, most allergen trials offered in Australia are into peanut allergy exclusively.<sup>17</sup>
- 5.22 Dr Kristin Perrett, Chief Investigator for CFAR, gave evidence that CFAR’s ‘next step’ would be the establishment of a food allergy clinical trial program which has the potential to be world leading. She stressed that this kind of research must be completed in a clinical setting to optimise patient safety.<sup>18</sup>
- 5.23 Dr Perrett is currently involved in a peanut patch immunotherapy trial through the Royal Children’s Hospital in Melbourne with Professor Mimi Tang. This trial has expanded from peanuts to researching egg and milk

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<sup>13</sup> Dr Hornung, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 24.

<sup>14</sup> ausEE Inc., *Submission 168*, pp. 9-10.

<sup>15</sup> Australian College of Nursing (ACN), *Submission 124*, p. 2.

<sup>16</sup> Name withheld, *Submission 148*, p. 2.

<sup>17</sup> Dr Kirsten Perrett, Chief Investigator, Centre for Food and Allergy Research (CFAR), *Committee Hansard*, Melbourne, 18 November 2019, p. 25.

<sup>18</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 24.

- allergy. Professor Robyn O’Hehir is conducting allergy research with peptides at the Royal Prince Alfred Hospital in Sydney.<sup>19</sup>
- 5.24 CFAR has conducted research into infant feeding which has led to significant changes in infant feeding guidelines. These new guidelines recommend earlier introduction of allergenic foods such as peanuts, eggs and dairy to infants, rather than avoiding them, which had been the previous recommendation.<sup>20</sup>
- 5.25 Ms Victoria Soriano, a PhD candidate at CFAR, has continued researching the impacts of this change to infant feeding guidelines. Her study looks at whether parents are following the new guidelines and has shown that allergenic foods such as peanuts and eggs are being introduced within the first year of life to children.<sup>21</sup>
- 5.26 Ms Soriano said that the outcome of the research into infant feeding guidelines will inform future research no matter what the outcome of the study is. If her study finds that earlier introduction of allergenic food does reduce childhood allergy then this will lead to a larger push for education of the new infant feeding guidelines. If there is no change to the prevalence of food allergy then CFAR’s researchers will know to focus on other risk factors for the development of childhood allergies.<sup>22</sup>
- 5.27 Dr Rachel Peters, from CFAR, stated that as of November 2019, there was a trial underway to determine if supplementing infants with vitamin D can prevent food allergy.<sup>23</sup>
- 5.28 Dr Peters said that there are trials looking into preventing eczema by improving the skin barrier and trials into allergen exposure at different sites in Australia. There are also trials ongoing looking into the rise of food allergies in Australia which will report ‘in the next couple of years’.<sup>24</sup>
- 5.29 Dr Perrett of CFAR stated that there are large gaps in Australia regarding research as well as surveillance. Increasing surveillance and reporting of

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<sup>19</sup> Dr Perrett , CFAR, *Committee Hansard*, Melbourne, 18 November 2019, pp. 25-26.

<sup>20</sup> Dr Rachel Peters, Researcher and Team Leader, Centre for Food and Allergy Research (CFAR), *Committee Hansard*, Melbourne, 18 November 2019, p. 28.

<sup>21</sup> Ms Victoria Soriano, PhD Candidate, Centre for Food and Allergy Research (CFAR), *Committee Hansard*, Melbourne, 18 November 2019, p. 27.

<sup>22</sup> Ms Soriano, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 29.

<sup>23</sup> Dr Peters, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 29.

<sup>24</sup> Dr Peters, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, pp. 30-31.

allergies from state-based registries could lead to a better understanding of risk factors, prevalence, diagnosis and management of food allergies. She said further that, with sustained funding, CFAR has the ability to play a role in not only filling these gaps but also producing world leading research.<sup>25</sup>

- 5.30 Dr Wong, from the Children's Hospital at Westmead, gave evidence that there is more research needed in Australia and that many clinical services in public hospitals had a strong interest in performing some of this research. However, due to the high level of need for clinical immunology and allergy services there is no time to perform this clinical research.<sup>26</sup>
- 5.31 The Molecular Allergy Research Laboratory at James Cook University is funded by the NHMRC. It has performed research into proteomics, molecular biology, bioinformatics and clinical immunology as they relate to allergic diseases. Its work has improved the understanding of the mechanism of allergic reactions as well as furthering information on the prevalence of allergies in Australia and Asia.<sup>27</sup>
- 5.32 Members of the Australian organisation TiARA (Tick Induced Allergies Research and Awareness) were the first researchers to find the link between tick bites and mammalian meat allergy (MMA) as well as doing research into the prevention of MMA through proper tick removal practices. A TiARA member also performed research into the use of personal repellents in order to prevent tick bites and MMA.<sup>28</sup>
- 5.33 At the Royal Adelaide Hospital there is a clinical trial into Jack Jumper Ant venom immunotherapy made with new adjuvants with an aim to reduce the amount of venom required for the therapy.<sup>29</sup> Ants must be 'milked' for venom to be used in immunotherapy which is a highly time consuming and labour intensive.<sup>30</sup>

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<sup>25</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 31.

<sup>26</sup> Dr Wong, The Children's Hospital at Westmead, *Committee Hansard*, Sydney, 19 November 2019, p. 21.

<sup>27</sup> Mr Shaymaviswanathan Karnaneedi, *Submission 122*, p. 1.

<sup>28</sup> Tick Induced Allergies Research and Awareness (TiARA), *Submission 137*, p. 6.

<sup>29</sup> Dr Pravin Hissaria, Immunology/allergy consultant/specialist, Clinical Immunology and Allergy Department, Royal Adelaide Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 20.

<sup>30</sup> Mrs Jennifer Gudden, Operations Manager, Jack Jumper Allergy Program, Royal Hobart Hospital, Tasmanian Health Service, *Committee Hansard*, Adelaide, 17 February 2020, p. 21.

- 5.34 The Allergy Research Group at the Queensland University of Technology (QUT) identified that there are many opportunities for research into allergic rhinitis comorbid with seasonal asthma. The Allergy Research Group stated that based on small-scale research, patients who have received grass pollen allergen immunotherapy for allergic rhinitis have a reduced reaction to thunderstorm asthma. Further funding for research is needed to expand on these findings as well as other factors which may influence the development of allergic rhinitis.<sup>31</sup>
- 5.35 The Allergy Research Group at QUT is also part of the AusPollen Aerobiology Collaboration Network. This group has implemented a pollen monitoring network across Australia through the contributions of researchers at numerous universities.<sup>32</sup> The AusPollen partnership is funded by the NHMRC until mid-2020 and is seeking to apply for further funding to continue its work into the future.<sup>33</sup>
- 5.36 There is limited funding for pollen collection around Australia. Professor Janet Davies, Head of the Allergy Research Group at the School of Biomedical Sciences and Institute of Health and Medical Innovation at the Queensland University of Technology stated that Australia has only 25 pollen monitoring stations compared to Europe's 600 stations and 87 stations in the United States.<sup>34</sup> She said further that the technology to monitor pollen in Australia is antiquated and highly labour intensive and that there is a strong need for innovation in this area in Australia.<sup>35</sup>
- 5.37 One submission suggested that pollen counts should be conducted earlier in the year than October in order to reduce the risks of allergies and improve asthma management.<sup>36</sup>
- 5.38 Dr Prathyusha Sanagavarapu is performing research at Western Sydney University into the mental health and wellbeing of parents and their allergy suffering children, in particular during the transition to school.<sup>37</sup>

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<sup>31</sup> Queensland University of Technology (QUT), *Submission 160*, p. 4.

<sup>32</sup> QUT, *Submission 160*, p. 5.

<sup>33</sup> Prof Janet Davies, Head, Allergy Research Group, School of Biomedical Sciences and Institute of Health and Medical Innovation, Queensland University of Technology, *Committee Hansard*, Brisbane, 18 February 2020, p. 33.

<sup>34</sup> Prof Davies, Queensland University of Technology, *Committee Hansard*, 18 February 2020, p. 33.

<sup>35</sup> Prof Davies, Queensland University of Technology, *Committee Hansard*, 18 February 2020, p. 34.

<sup>36</sup> Mr Craig Blinco, *Submission 29*, p. 1.

### *Patient/Parent perspectives*

- 5.39 The Committee received evidence from patients, the parents of patients and prospective subjects of research trials. Parents and patients had a high level of interest in participating in research trials for food allergy but often found it difficult to find information about trials or found the trials too restrictive to take part in.
- 5.40 Mrs Linda Norwood stated she chose for her son to take part in a peanut immunotherapy patch trial as it appeared to be the only choice for him available in Australia. Another factor in confirming this decision for her was that only 30 per cent of participants would be given placebos, which would increase her son's chance of getting an active dose of the treatment. She noted that taking part in a research trial restricted other treatment options, such as undertaking food challenges for her son's other allergies, and highlighted the increasing incidence of patients on the trial having anaphylactic episodes during treatment.<sup>38</sup>
- 5.41 Mrs Norwood also noted that, if given the opportunity to take part in a trial where there was no placebo option, she would find that a more attractive option.<sup>39</sup>
- 5.42 Mrs Maria Stipic had similar sentiments. She was considering enrolling her three-year-old child in a trial in Melbourne, and the time commitment plus the distance she lived from the hospital made this a large commitment. She also stated that she would be much more likely to take part in a trial that had no placebo.<sup>40</sup>
- 5.43 Several submitters commented they would like information about clinical trials and different treatment options to be more readily available.<sup>41</sup>
- 5.44 One submitter noted that they had learned about current treatment options and research trials from being a member of patient advocacy groups like A&AA rather than from their allergist.<sup>42</sup>

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<sup>37</sup> Dr Prathyusha Sanagavarapu, *Submission 175*, pp. 5-6.

<sup>38</sup> Mrs Linda Norwood, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, pp. 7-8.

<sup>39</sup> Mrs Norwood, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 8.

<sup>40</sup> Ms Maria Stipic, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 8.

<sup>41</sup> Name withheld, *Submission 73*, p. 4; Name withheld, *Submission 44*, pp. 2-3.

<sup>42</sup> Name withheld, *Submission 75*, p. 2.

- 5.45 Another person stated that they have closely followed available research trials in Australia since 2015 but have been frustrated by appropriate trials being in different states or their children not being in the age bracket required.<sup>43</sup>
- 5.46 One submitter suggested they would like to see more research into ‘environmental changes and medical advances and how these may be affecting our bodies in an adverse way.’ They also said that often research into allergies has a siloed approach and lacks a broader vision.<sup>44</sup>

### *Peak body perspectives on the future of research*

- 5.47 The National Allergy Strategy (NAS) stated that it would like to see more research into the services and resources required by allergy sufferers in order to increase safety and make the anxiety felt by allergy sufferers more manageable.<sup>45</sup>
- 5.48 The peak organisation for allergy patients, A&AA provided a list of areas they would like to see further research into:
- the psychosocial aspects of severe allergy, recovery from a life threatening events of anaphylaxis, and other quality of life matters;
  - the risk of allergic or anaphylactic reactions from touch, smell or airborne ingestion;
  - the gaps in care and support for families after a fatal allergic reaction;
  - improved diagnostic tools and prediction markers for the severity of anaphylaxis, including research into why some allergy sufferers grow out of their allergies and others do not;
  - the number of doses of adrenaline required during an anaphylactic episode as well as the stability of adrenaline auto injectors above 25 degrees Celsius (manufacturer warnings indicate adrenaline auto-injectors should be kept between 15–25 degrees Celsius);
  - the prevalence, diagnosis and current treatment options for non IgE mediated food allergy;
  - patient management of atopic dermatitis and allergic rhinitis, including patient compliance with treatment regimens;
  - the relationship between tick bites and mammalian meat allergy (MMA), including the prevalence of MMA in Australia; and

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<sup>43</sup> Name withheld, *Submission 10*, p. 1.

<sup>44</sup> Name withheld, *Submission 80*, p. 3.

<sup>45</sup> National Allergy Strategy (NAS), *Submission 118*, p. 19.

- prevalence data on all allergic disease states in Australia.<sup>46</sup>

### *Overseas research and collaboration*

5.49 Dr Perrett of CFAR stated they have close working relationships with researchers in the United Kingdom and the United States of America. She said:

These people regularly come to our strategic update days where we bring the collaboration together to inform best practice on what's happening around the world. We're setting up some very key links with people in terms of trials and trial design to think about embedding treatment into routine care.<sup>47</sup>

5.50 Dr Perrett also said CFAR was looking to apply for funding from the MRFF or other sources in order to work closely with overseas research centres which are currently doing treatment trials and bring that knowledge to Australian clinical care.<sup>48</sup>

## **Oral immunotherapy (OIT) in Australia**

### *Overview*

5.51 Oral immunotherapy (OIT) treatments for severe allergies was a frequently raised topic in submissions.

5.52 Food Allergy Goals stated that 'OIT involves planned and managed incremental exposure to known allergens under controlled conditions over many months to provoke desensitisation.'<sup>49</sup>

5.53 This treatment has been offered through clinical trials and research projects overseas for a number of years and in many cases seems to have significantly lowered the risk of severe anaphylaxis in highly sensitive patients.<sup>50</sup>

5.54 OIT can be done in two ways:

- Food immunotherapy, where small portions of food as used to desensitise the patient; or

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<sup>46</sup> Allergy and Anaphylaxis Australia (A&AA), *Submission 184*, pp. 21-22.

<sup>47</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 25.

<sup>48</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 26.

<sup>49</sup> Food Allergy Goals, *Submission 47*, p. 1.

<sup>50</sup> Food Allergy Goals, *Submission 47*, p. 1.

- Pharmacological immunotherapy, where the allergen is presented to the body through a pharmaceutical, such as a patch or pill.<sup>51</sup>

5.55 Immunotherapy for venom anaphylaxis (venom immunotherapy or VIT) operates on a similar principal to OIT, with treatment being increased doses of insect venom in order to create tolerance. OIT for Jack Jumper Ant is currently being run in Tasmania, Victoria and South Australia.<sup>52</sup>

### *Consideration of OIT in Australia (Medical specialist perspectives)*

5.56 Most of the evidence received by the Committee was concerned with limited or no access to food based oral immunotherapy in Australia. Unless otherwise stated, the term oral immunotherapy or OIT will refer to food oral immunotherapy.

5.57 ASCIA submitted that OIT is currently only available in clinical research settings, though the field is expanding rapidly. Overseas, OIT is often a part of clinical care for allergy sufferers and many Australian families have relocated to countries where OIT is offered clinically in order to have access to this treatment.<sup>53</sup>

5.58 ASCIA stressed the need for OIT to be performed safely and responsibly and the importance of quality, peer reviewed research before OIT is rolled out at a clinical level in Australia. It also stated that it would be impossible to meet demand for OIT in Australia due to the lack of an MBS item number for food allergen challenges.<sup>54</sup>

5.59 ASCIA also stated that OIT does not provide a cure for allergies for most patients and side effects include possible anaphylaxis. As such, 'further assessment of safety, patient selection and appropriate use in Australia is required.'<sup>55</sup>

5.60 The NAS described OIT as a 'promising strategy' for the management of allergy and reduction of the risk of anaphylaxis leading to improved quality of life for many allergy sufferers. It echoed ASCIA's concerns however, about the risks of side effects from the therapy and the importance of expert supervision. It stated that more research into this area is need in Australia

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<sup>51</sup> Food Allergy Goals, *Submission 47*, p. 1.

<sup>52</sup> Royal Adelaide Hospital, *Submission 178*, p. 2.

<sup>53</sup> ASCIA, *Submission 153*, p. 4.

<sup>54</sup> ASCIA, *Submission 153*, p. 4.

<sup>55</sup> ASCIA, *Submission 153*, p. 4.

and that individuals should be aware of the risks before undertaking such a course of treatment.<sup>56</sup>

- 5.61 A&AA submitted that there were three times more anaphylactic reactions for patients undergoing OIT than for patients avoiding the allergen.<sup>57</sup>
- 5.62 ausEE Inc., a patient advocacy group for sufferers of Eosinophilic Oesophagitis, is supportive of OIT but would like patients to be aware that developing Eosinophilic Oesophagitis can be a side effect of undergoing OIT. They stated that potential patients should be aware of the risks of development Eosinophilic Oesophagitis during OIT and clinicians should investigate gastrointestinal symptoms of patients through the course of the treatment.<sup>58</sup>
- 5.63 A&AA stated that any patient seeking to undergo OIT should first undertake a food challenge in order to determine if they are truly allergic to the food. It went on to say that waitlists for food challenges in Australian hospitals were already very long and that any treatment program not offering a cure should not be allowed to further worsen these waiting times.<sup>59</sup>
- 5.64 A&AA continued by stating that it believes OIT requires more research and a standardised treatment regimen, but it is supportive of expediting current research and overseas treatment regimens so they can be made available in Australia.<sup>60</sup>
- 5.65 Dr Kirsten Perrett of CFAR stated that OIT leads to desensitisation to the treated allergen in the majority of children and adults who undertake OIT, but there are significant safety concerns. She did not believe that OIT was ready to be offered clinically in Australia.<sup>61</sup>
- 5.66 Dr Perrett stated further that the desensitisation caused by OIT was a temporary state that could be affected by changes in the patient's immune system. The risk of an anaphylactic reaction while on OIT could be affected by having a fever or infection, menstruation, or simply having a higher body

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<sup>56</sup> NAS, *Submission 118*, p. 8.

<sup>57</sup> A&AA, *Submission 184*, pp. 20-21.

<sup>58</sup> ausEE Inc., *Submission 168*, p. 10.

<sup>59</sup> A&AA, *Submission 184*, p. 20.

<sup>60</sup> A&AA, *Submission 184*, p. 21.

<sup>61</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, pp. 23-24.

temperature due to exercise. While a small minority of children and adults who undertook OIT entered a long term remission in their allergy, this group of people are by far the minority.<sup>62</sup>

- 5.67 Although it was too early to offer OIT in a clinical setting in Australia, Dr Perrett stated that it would be appropriate to offer OIT in a trial scenario where it could be closely monitored, supervised and evaluated. Such a trial scenario would not be limited in the way a typical clinical trial is limited and would be offered through hospitals to any patient who wanted to go through the process.<sup>63</sup>
- 5.68 When asked how this process would differ from a clinical care rollout if it was offered to every allergy patient and not restricted, Dr Perrett answered that there would be research into the results, enhanced monitoring, follow-up, and rigorous supervision of the process of the treatment. She stressed there are too many unknowns to offer OIT in a clinical setting at this stage.<sup>64</sup>
- 5.69 Dr Dean Tey, a paediatric immunologist appearing in a private capacity, stated that Australian families should not have to travel overseas in order to access OIT, but stated the importance of administering this new treatment with clinical oversight and research so that therapies can be refined and made safer.<sup>65</sup>
- 5.70 Dr Tey said further that there were ethical concerns with OIT. Is it ethical to ask an OIT patient to stop eating their allergen for two months and then eat it to see if their allergic unresponsiveness was permanent, putting the patient at risk for a dangerous anaphylactic response? He went on to say that when dealing with anaphylaxis, there is a need for a high level of certainty before declaring remission and more long term research is required.<sup>66</sup>
- 5.71 Dr Perrett of CFAR set out three main barriers to the implementation of OIT in Australia:
- Access: any clinical implementation of OIT would have access issues, as allergy clinics in Australia are already overwhelmed by demand and

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<sup>62</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 25.

<sup>63</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 31.

<sup>64</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, pp. 31-32.

<sup>65</sup> Dr Dean Tey, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 55.

<sup>66</sup> Dr Tey, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, pp. 58-59.

struggle to provide current treatments, such as food challenges. Any trial of OIT would need to be separately funded from current allergy clinics.

- Efficacy: there are still many unknowns with OIT, such as the correct amount to 'updose' the allergen while undergoing treatment, correct maintenance doses, what foods can be treated concurrently, and whether new adjuvants provide benefits to the treatment.
- Safety: recent research published in *the Lancet* has shown the risk of anaphylaxis is three times more likely while a patient is undergoing OIT.<sup>67</sup>

### ***Support for OIT in Australia (Patient/parent perspectives)***

- 5.72 The Committee received a lot of evidence from parents and patient advocacy groups calling for an immediate introduction of OIT in Australia.
- 5.73 Mrs Melissa Mooney of Food Allergy Goals commented that a systemic implementation of OIT, rather than the ad hoc development that has occurred in the United States, would be preferable in Australia.<sup>68</sup>
- 5.74 Mrs Mooney gave evidence that there is a lack of balance in the discussion surrounding OIT in Australia. She contrasted articles published in *the Lancet* medical journal that were highly critical of OIT with the experiences of patients and their families who have undergone OIT in the United States and had found it highly successful. She emphasised that OIT was not a treatment for everyone but considering its success stories it needed to be explored in Australia.<sup>69</sup>
- 5.75 Mrs Simone Albert, of Food Allergy Goals, whose son had also undergone OIT overseas for four allergens, stated that OIT is a robust treatment that requires a large time commitment and is not for everybody. Prospective patients in Australia would need informed consent, particularly around the psychological aspects involved.<sup>70</sup> She further described the treatment as arduous for the patient but fairly simple in administration.<sup>71</sup>
- 5.76 Mrs Albert went on to say that since her son had completed the initial OIT regimen and was now in maintenance he had not had an anaphylactic

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<sup>67</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 32.

<sup>68</sup> Mrs Melissa Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 52.

<sup>69</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 51.

<sup>70</sup> Mrs Simone Albert, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 6.

<sup>71</sup> Mrs Albert, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 7.

reaction. Previous to OIT, he had averaged one anaphylactic episode a year.<sup>72</sup>

- 5.77 Dr Emily Amos reinforced the view that OIT had to be a personal decision for the patient and their family. Dr Amos stated that undergoing OIT for her daughter would not be right for her family due to distance from a large hospital and other factors, but might be something she considers in the future.<sup>73</sup>
- 5.78 Mrs Melissa Mooney of Food Allergy Goals said that due to the probable lengthy time before the pharmaceutical immunotherapy being trialled in Australia was available to the public, there was a generation of children who would miss out on this treatment option. As such, it was important to give food based OIT thorough consideration as a treatment option.<sup>74</sup>
- 5.79 Mrs Mooney said further that this generation of allergy children are approaching adolescence, 'heading into what is the most dangerous phase' and that this generation needed treatment options like OIT.<sup>75</sup>
- 5.80 Mrs Mooney stated that education about the severity of side effects would be very important for patients starting on an OIT protocol, and that the high incidence of side effects for patients undergoing OIT was sometimes used to scare people away from the treatment, but increased levels of education and support would allay those fears.<sup>76</sup>
- 5.81 Mrs Simone Albert gave evidence that, after undergoing OIT, many of the issues around labelling and traces of food present in packaged food are no longer an issue for her family due to her son's desensitisation. She also said that some people have improved asthma and allergic rhinitis symptoms after undergoing OIT<sup>77</sup> and that research has shown that IgE levels have decreased following OIT treatment.<sup>78</sup>
- 5.82 Another submission stated that there is anecdotal evidence that patients in maintenance post OIT have reduced asthma symptoms and are also less

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<sup>72</sup> Mrs Albert, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 7.

<sup>73</sup> Dr Emily Amos, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 7.

<sup>74</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 51.

<sup>75</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 52.

<sup>76</sup> Mrs Albert, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 52.

<sup>77</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 53.

<sup>78</sup> Mrs Albert, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 53.

likely to get colds and flu, with leads to improvements in school attendance for children. There are also less tangible benefits, like improvement in confidence and other psychological benefits.<sup>79</sup>

- 5.83 Mrs Mooney suggested that funding for the rollout of OIT would decrease the burden on the hospital system for providing oral food challenges and care for people during and after anaphylactic episodes.<sup>80</sup>
- 5.84 Mrs Mooney added that undergoing OIT is particularly attractive for patients who have multiple severe allergies, frequently experience anaphylaxis and have a significantly affected quality of life.<sup>81</sup>
- 5.85 Mrs Mooney also gave evidence about taking part CFAR's roundtable on OIT, stating that although there was movement in the right direction, the possibility of OIT being trialled in Australia still seemed far away. Funding and certainty of patient outcomes seemed to be barriers to medical professionals accepting OIT as a treatment option.<sup>82</sup>
- 5.86 The Committee received numerous submissions from patients and their families requesting that oral immunotherapy be made available in Australia<sup>83</sup> or that more funding for research into this therapy be made available for trials.<sup>84</sup>
- 5.87 Some submitters expressed frustration at how OIT was available in Singapore and the United States but not available in Australia, saying the cost was prohibitive for them to undertake the therapy overseas.<sup>85</sup>
- 5.88 Other people were more sceptical about OIT. One submission noted that the desensitisation of OIT would only work up to a point and that in some patients it can increase the risk of anaphylaxis. They suggested that better education about the topic would 'help bring a sense of security and power

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<sup>79</sup> Name withheld, *Submission 131*, p. 2.

<sup>80</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 53.

<sup>81</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 53.

<sup>82</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 54.

<sup>83</sup> Name withheld, *Submission 12*, p. 4; Name withheld, *Submission 55*, p. 3; Name withheld, *Submission 73*, p. 4; Name withheld, *Submission 181*, p. 2.

<sup>84</sup> Dr Robyn Stephenson, *Submission 28*, p. 6; Dr Paxton Loke, *Submission 234*, p. 1.

<sup>85</sup> Name withheld, *Submission 17*, p. 3; Name withheld, *Submission 150*, p. 2.

rather than the current feeling of panic among allergy sufferers that there is help available and we are being denied it.’<sup>86</sup>

- 5.89 Mrs Carolina Valerio said one of her major concerns with her child undergoing OIT was the risk of developing eosinophilic oesophagitis (EoE) during or after treatment. She advocated for more research both into OIT and EoE, as EoE is a poorly understood disease.<sup>87</sup>
- 5.90 Another submission to the inquiry had the opposite view. The submitter stated they would happily take the risk of an ‘additional [anaphylactic] reaction or two’ if their son was able to freely eat their allergen after the treatment.<sup>88</sup>
- 5.91 Ms Maria Stipic wrote in her submission that although there is a strong research emphasis on finding a cure for allergies in Australia, most parents who consider OIT for their children view it as a treatment. Reducing the risk of an anaphylactic reaction in severely allergic individuals already provides a great improvement in quality of life.<sup>89</sup>

## Current practice and research

- 5.92 The Committee also received evidence about the state of current research into OIT in Australia, including some doctors currently practicing this therapy.
- 5.93 Ms Maria Said, Chief Executive Officer of A&AA said she was aware of three to four doctors who were providing OIT outside of a research setting. She gave evidence of one health professional that has no training in allergy or immunology providing OIT to patients. She emphasised that A&AA liked to work alongside ASCIA and follow their recommendations around research and emerging treatments. A&AA is also concerned by the lack of long term research into the effects of OIT on patients.<sup>90</sup>
- 5.94 Immunotherapy for non-food allergies is already offered at a clinical level in Australia. Dr Suzan Bekir, Clinical Director of the Australian Allergy Centre

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<sup>86</sup> Name withheld, *Submission 48*, p. 4.

<sup>87</sup> Mrs Valerio, private capacity, *Committee Hansard*, Sydney, 19 November 2019, p. 5.

<sup>88</sup> Name withheld, *Submission 157*, p. 1.

<sup>89</sup> Ms Stipic, *Submission 18*, p. 4.

<sup>90</sup> Ms Maria Said, Chief Executive Officer, Allergy and Anaphylaxis Australia (A&AA), *Committee Hansard*, Sydney, 19 November 2019, p. 26.

stated that non-food immunotherapy is currently being offered for dust mites and grass pollen allergies.<sup>91</sup>

- 5.95 Professor Robyn O’Hehir of Alfred Health said she is currently working on research into peanut peptide oral immunotherapy but stressed the need to go through the full regulatory process as patient safety was a high concern. She also stated that peanut OIT is a practiced globally but is a research tool in Australia.<sup>92</sup>
- 5.96 Dr Joanne Smart at the Royal Children’s Hospital in Melbourne said that OIT will be available in Australia in the future but the issue will be resourcing, as current allergy and immunology clinics already struggle to keep up with the needs of the community.<sup>93</sup>
- 5.97 This view was echoed by Professor Michael Gold, from the Women’s and Children’s Hospital in Adelaide, who said that food OIT would ‘create a huge demand and burden on the public system.’<sup>94</sup>
- 5.98 Aside from doing research into food based OIT, CFAR is also doing research into immunotherapy using novel adjuvants, peptide vaccines and other pharmaceuticals which are currently being trialled and may have longer term effects for patients.<sup>95</sup>
- 5.99 Dr Perrett discussed with the Committee trials examined in *the Lancet* all involved older children and adults:

... there has been a large meta-analysis done recently and published in *The Lancet* of 12 studies of food oral immunotherapy trials. That has shown serious concerns with adverse events in terms of a three-times increased risk of having anaphylaxis while you are on oral immunotherapy than if you avoid the food. At the moment those trials are done on older children and adults.

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<sup>91</sup> Dr Suzan Bekir, Clinical Director, Australian Allergy Centre, *Committee Hansard*, Sydney, 19 November 2019, p. 57.

<sup>92</sup> Prof Robyn O’Hehir, Director, Department of Allergy, Immunology and Cystic Fibrosis, Alfred Health; Head of Department, Allergy, Clinical Immunology and Respiratory Medicine, Central Clinical School, Monash University, *Committee Hansard*, Melbourne, 18 November 2019, p. 21.

<sup>93</sup> Dr Joanne Smart, Director, Department of Allergy and Immunology, Royal Children’s Hospital, *Committee Hansard*, Melbourne, 18 November 2019, p. 21.

<sup>94</sup> Prof Michael Gold, Senior Consultant, Department of Allergy and Clinical Immunology, the Women’s and Children’s Hospital, *Committee Hansard*, Adelaide, 17 February 2020, p. 8.

<sup>95</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 25.

What we are looking at is a model of a pragmatic trial done with a younger age group where we believe oral immunotherapy can harness the modulation of the immune system at a younger age. Pragmatic trials in this type of way have been done in Canada and they show a far better efficacy in terms of desensitisation, fewer side effects and a better safety profile for that younger age group.<sup>96</sup>

5.100 However, any trials into OIT would have to be publicly funded, as the nature of food immunotherapy means there is no pharmaceutical product which a company could invest in by funding research.<sup>97</sup>

5.101 Mrs Melissa Mooney of Food Allergy Goals gave evidence that a group of Canadian doctors doing an OIT trial with preschool aged children had provided ‘much more balanced’ view of OIT versus pure avoidance:

Allergists and the medical community as a whole must stop confusing parents with endless mixed messages about OIT both within and outside of research. The fact is, many allergists are already offering OIT outside of research. In our current era of basing medical treatment decisions on a comparison of risks versus benefits, there is simply no one-size-fits-all approach.

...telling parents of children with peanut allergy that avoidance is the only option outside research fails to take into account the negative long-term consequences of avoidance – such as poor quality of life, social isolation and anxiety.<sup>98</sup>

5.102 Several submissions to the inquiry mentioned the probiotic and peanut allergy OIT research undertaken at the Murdoch Children’s Research Institute (MCRI) in Melbourne, requesting that this research get funding and the results be expedited.<sup>99</sup>

5.103 Another submitter asked that the MCRI probiotic and peanut OIT research and the Westmead Children’s Hospital peanut OIT trial be expanded to include other major allergens, including tree nuts.<sup>100</sup>

5.104 One submission expressed frustration at the time required for the MCRI’s study to become a viable treatment as part of clinical practice, noting that

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<sup>96</sup> Dr Perrett, CFAR, Committee Hansard, Melbourne, 18 November 2019, p. 32.

<sup>97</sup> Dr Perrett, CFAR, *Committee Hansard*, Melbourne, 18 November 2019, p. 32.

<sup>98</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 51.

<sup>99</sup> Name withheld, *Submission 10*, p. 1; Name withheld, *Submission 34*, p. 2.

<sup>100</sup> Name withheld, *Submission 34*, p. 2.

there is evidence OIT is more effective in children. The submitter had concerns by the time the therapy was generally available it would be too late for any treatment to be effective on their son.<sup>101</sup>

### **Overseas oral immunotherapy (OIT)**

5.105 The Committee received a large amount of evidence from families who had travelled overseas, primarily to the United States, to receive OIT.

5.106 Mrs Linda Norwood gave evidence of her son receiving OIT for peanut and cashew allergies in the United States over a period of two years. As a result of this treatment, he can now eat two peanuts and two cashews a day, compared to previously where he had an anaphylactic reaction to traces of nuts in a hot chocolate drink. This has led to significant improvements in the family's quality of life, reducing stress and anxiety around eating and travel.<sup>102</sup>

5.107 In her submission Mrs Norwood said:

Our son is so much safer now, and his food options have really increased. Although he can't eat handfuls of his allergens, he can eat foods with cross contamination and traces. He doesn't react on contact any more. He loves trying all the new foods that were off limits before. He can join in birthdays and other celebrations without needing to bring his own food. Eating out and travelling are much more relaxing and enjoyable experiences for the whole family. Although he is still considered allergic and needs to carry Epipens, his life is much freer now because his tolerance to his allergens is so much higher. He is less likely to have a severe reaction to accidental exposure. His quality of life and anxiety around food has greatly improved since the treatment.<sup>103</sup>

5.108 Mrs Albert of Food Allergy Goals confirmed that OIT has been practiced for over ten years in both a private and public setting in the United States. As well as being offered in some hospitals in the United States, it is also offered in children's hospitals in Singapore, Canada, Hong Kong, and other places. OIT is also offered in a research setting in the United Kingdom, but is still open to the public.<sup>104</sup>

5.109 Mrs Catherine Sly, a parent of a child who had undergone OIT, said that the way OIT is offered can vary. Some people go through the process faster,

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<sup>101</sup> Name withheld, *Submission 74*, p. 2.

<sup>102</sup> Mrs Norwood, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 4.

<sup>103</sup> Mrs Linda Norwood, *Submission 35*, p. 1.

<sup>104</sup> Mrs Albert, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 6.

moving to larger doses of the allergen at a quicker pace and complete the treatment in only a few months. Others need more time between doses and have a more difficult experience, experiencing mild allergic reactions like mouth tingling and stomach pain. Mrs Sly reported that her daughter's doctor had given 4,000 up-doses in his practice and has never had to use an EpiPen for an anaphylactic reaction.<sup>105</sup>

- 5.110 Mrs Sly said she would have preferred to undergo OIT in Australia and that pursuing the treatment overseas has been difficult in many ways. In Australia they would have had family and community support and would not have had to split their family between two countries. Despite these difficulties, she described OIT as life changing for their daughter; stating she could now go to birthday parties and eat the cake, enjoys pizza and chocolate and was generally happier and less anxious. Her daughter's immunotherapy maintenance is done through peanuts bought from supermarkets.<sup>106</sup>
- 5.111 Mrs Norwood said that part of what caused her to look into OIT overseas was that several allergies could be treated concurrently. In Australia, her son had taken part in the Westmead Children's Hospital peanut patch immunotherapy trial and found improvement in his peanut allergy however, 'having done just the peanut trial but still being allergic to other allergens didn't change our life as much as the oral immunotherapy did.'<sup>107</sup>
- 5.112 Mrs Mooney of Food Allergy Goals said that Canada was a good example of allergy parents and doctors working together to make OIT available. In Quebec, a doctor wanted to expand his current trials on OIT and asked parents to help him fundraise with the aim of having the provincial government match their donations. The parents group raised \$750,000 which was then matched by the Quebec government and allowed the expanded trial to start.<sup>108</sup>
- 5.113 The doctor in charge of the pilot is working with the Canadian Society of Allergy and Clinical Immunology to create protocols for clinical use with a view to a national rollout of OIT in Canada. Mrs Mooney stated this process,

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<sup>105</sup> Mrs Catherine Sly, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, p. 4.

<sup>106</sup> Mrs Sly, private capacity, *Committee Hansard*, Brisbane, 18 February 2020, pp. 2-3.

<sup>107</sup> Mrs Norwood, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, pp. 8-9.

<sup>108</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 54.

involving government, doctors, patient groups and professional peak bodies, is an example of how OIT could be implemented in Australia.<sup>109</sup>

- 5.114 Dr Dean Tey noted that OIT had about an 80 per cent success rate for desensitisation towards the allergen. There is roughly a 10 to 20 per cent dropout rate in OIT trials for patients who found the therapy too taxing or had had anaphylactic reactions during treatment. Rates for sustained unresponsiveness or remission of the allergy are much lower, between 50 and 80 per cent depending on the trial and the allergen being treated.<sup>110</sup>
- 5.115 Dr Tey also said that the national guidelines for allergy in Australia and the United States of America both state that OIT should not be practiced clinically outside of research setting. There is less clarity about the practice in Europe and Japan. However, he is not aware of Australian families travelling to Japan or Europe to access OIT, only the United States.<sup>111</sup>
- 5.116 The Committee received several submissions from parents of children with severe allergies asking why OIT was not available in Australia and referencing success stories they had read online about undergoing OIT.<sup>112</sup> Many people stated they would like OIT made available in Australia.<sup>113</sup> There were also several submissions from families planning to make the trip to the United States for treatment in the near future.<sup>114</sup>
- 5.117 One submission stated the family had already travelled to the United States for sublingual immunotherapy (SLIT)<sup>115</sup> for their daughter which had been successful in reducing her allergies. That family is now planning to make another trip to the United States for OIT to treat her remaining anaphylactic allergy.<sup>116</sup>

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<sup>109</sup> Mrs Mooney, Food Allergy Goals, *Committee Hansard*, Melbourne, 18 November 2019, p. 54.

<sup>110</sup> Dr Tey, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 58.

<sup>111</sup> Dr Tey, private capacity, *Committee Hansard*, Melbourne, 18 November 2019, p. 59.

<sup>112</sup> Ms Nikki Brown, *Submission 9*, p. 1.

<sup>113</sup> Name withheld, *Submission 43*, p. 3; Mrs Cindy Egan, *Submission 194*, p. 1; Name withheld, *Submission 202*, p. 4.

<sup>114</sup> Name withheld, *Submission 117*, p. 2; Name withheld, *Submission 119*, p. 2.

<sup>115</sup> SLIT is a form of immunotherapy where tablets are placed under the tongue. The United States Food and Drug Administration currently only approves SLIT for the treatment of ragweed, grass and dust mite allergies; American College of Allergy, Asthma & Immunology, 'Sublingual Immunotherapy (SLIT)' <<https://acaai.org/allergies/allergy-treatment/allergy-immunotherapy/sublingual-immunotherapy-slit>> viewed 11 February 2020.

<sup>116</sup> Name withheld, *Submission 117*, p. 2.

- 5.118 Mrs Simone Albert also gave evidence about choosing to undergo OIT for her son in America. Her son had severe allergies to dairy, egg, wheat, rye, peanuts, and other allergens, leading the family to make the decision to undergo OIT. They documented this process through their Facebook page Oliver's Choice in the hopes it would encourage Australian medical bodies to introduce the treatment in Australia.<sup>117</sup>
- 5.119 One submitter wrote that they explored undergoing OIT in Singapore for their daughter but chose not to due to the risks and high costs of undergoing overseas treatment.<sup>118</sup>
- 5.120 Ms Kym Banjac gave evidence about her plans to relocate to the United States for a year for her daughter Mila's OIT treatment. She emphasised that despite the risks of increased anaphylaxis, she still wants to undergo OIT, saying:
- Because we no longer want our allergy children, our non-allergy siblings and ourselves to live in fear every single day. And believe me, we do. I do. My husband does. My boys do. We are terrified that the next mistake might take Mila's life. And there is no respite from that stress. It is with us 24 hours a day, every day of our lives.<sup>119</sup>
- 5.121 Ms Emily Marney wrote from the United States where her son Angus was undergoing OIT for dairy and peanut allergy. She has already seen improvements in his reactions to dairy and peanuts and feels that the OIT treatment is safer than food challenges offered in Australian hospitals. In order to afford to travel to the US for treatment the family created a Go Fund Me crowdfunding page, held community events and had donation tins in local shops and restaurants. She describes the decision to undertake OIT as an 'investment into Angus' future allowing him the freedom to choose any career, go on school camps, sleepovers and live a life free of anxiety and food aversions.'<sup>120</sup>

## Support for dupilumab

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<sup>117</sup> Ms Simone Albert, *Submission 37*, p. 2.

<sup>118</sup> Name withheld, *Submission 52*, pp. 4-5.

<sup>119</sup> Mrs Kym Banjac, *Submission 88*, p. 2.

<sup>120</sup> Ms Emily Marney, *Submission 212*, pp. 4-5.

- 5.122 The Committee received a large amount of evidence about the new medication dupilumab (trade name Dupixent), a monoclonal antibody injection typically used to treat severe eczema.<sup>121</sup>
- 5.123 Dupilumab is administered by injection and is approved for prescription for people aged 12 and over with a cost of \$1,600 a month.<sup>122</sup> This therapy has been on the publicly funded health system in the United Kingdom since 2018.<sup>123</sup>
- 5.124 The Department of Health confirmed that Sanofi, the manufacturer of dupilumab, had applied to Pharmaceutical Benefits Advisory Committee (PBAC) for listing of the therapy on the Pharmaceutical Benefits Scheme (PBS) in July 2018 and July 2019. Although PBAC acknowledged the clinical need for treatments for moderate to severe eczema, it did not recommend dupilumab for listing at those meetings.<sup>124</sup>
- 5.125 Professor Constance Katelaris at Campbelltown Hospital stated that dupilumab has ‘astounding’ trial data and a very good safety profile. It also has less harmful side effects than the immunosuppressant agents which are typically prescribed to treat severe eczema.<sup>125</sup>
- 5.126 Professor Katelaris said she had been able to access dupilumab for 12 patients. All have reported excellent results, describing it as ‘life changing.’ Three of her patients have reported one side effect, worsening ocular allergy, but have been able to control it working with ophthalmologists. Even those patients who experienced this side effect would not stop treatment as it has been so effective.<sup>126</sup>
- 5.127 Professor Katelaris did concede that the treatment of eczema with dupilumab is expensive with ongoing fortnightly injections costing \$800 or \$900. However, in contrast, other eczema treatments such as cyclosporine or

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<sup>121</sup> Associate Prof Michael Sladden, *Submission 50*, p. 1.

<sup>122</sup> Mrs Melanie Funk, Managing Director and Founder, Eczema Support Australia, *Committee Hansard*, Brisbane, 18 February 2020, p. 29.

<sup>123</sup> Mrs Funk, Eczema Support Australia, *Committee Hansard*, Brisbane, 18 February 2020, pp. 26-27.

<sup>124</sup> DoH, *Submission 78.2*, Answer to Question on Notice, pp. 11-12.

<sup>125</sup> Prof Constance Katelaris, Head of Unit, Immunology and Allergy, Campbelltown Hospital, *Committee Hansard*, Sydney, 19 November 2019, p. 41.

<sup>126</sup> Prof Katelaris, Campbelltown Hospital, *Committee Hansard*, Sydney, 19 November 2019, p. 42.

methotrexate, have severe side effects, including hypertension, renal disease and the possibility of developing cancer.<sup>127</sup>

- 5.128 Many eczema sufferers and their families wrote to the Committee urging for the PBAC to list dupilumab on the PBS. Many noted the high cost of the therapy and that they would not be able to afford it without it being listed on the PBS.<sup>128</sup>
- 5.129 Mrs Funk of Eczema Support Australia reported that she had heard from members of her organisation that dupilumab had reduced their symptoms by 90 to 100 per cent. The first person she met who was on the drug 'was bouncing off the walls with joy and wanting to shout from the rooftops.'<sup>129</sup> Another of her members whose eczema had previously been treated with chemotherapy drugs and had to stop due to organ failure was now on dupilumab and his only side effect was dry eye.<sup>130</sup>
- 5.130 Mrs Funk also said a change.org petition had attracted three thousand signatures asking for dupilumab to be added to the PBS. Many of the comments under this petition noted the suffering of people with severe eczema and desperation they feel without this medication.<sup>131</sup>
- 5.131 One person who was undergoing dupilumab treatment wrote saying that their productivity has doubled since starting receiving the injections. Their sleep has improved due to the reduction of eczema on their scalp, they take less time off work, and can perform more everyday tasks like driving and cleaning.<sup>132</sup>
- 5.132 Sanofi made a further application for to PBAC to list dupilumab on the PBS which was considered in PBAC's March 2020 meeting.<sup>133</sup> In that meeting the PBAC '...recommended the listing of dupilumab for the treatment of

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<sup>127</sup> Prof Katelaris, Campbelltown Hospital, *Committee Hansard*, Sydney, 19 November 2019, p. 42.

<sup>128</sup> Name withheld, *Submission 232*, p. 2; Name withheld, *Submission 177*, p. 2; Name withheld, *Submission 128*, p. 1; Name withheld, *Submission 7*, p. 2; Name withheld, *Submission 51*, p. 4.

<sup>129</sup> Mrs Funk, Eczema Support Australia, *Committee Hansard*, Brisbane, 18 February 2020, p. 30.

<sup>130</sup> Mrs Funk, Eczema Support Australia, *Committee Hansard*, Brisbane, 18 February 2020, p. 31.

<sup>131</sup> Mrs Funk, Eczema Support Australia, *Committee Hansard*, Brisbane, 18 February 2020, pp. 26-27.

<sup>132</sup> Name withheld, *Submission 223*, p. 2.

<sup>133</sup> DoH, *Submission 78.2*, Answer to Question on Notice, p. 12.

patients aged 12 years and older with severe atopic dermatitis who are inadequately controlled on topical therapies.’<sup>134</sup>

### *Other emerging therapies*

- 5.133 The Committee received evidence about some other emerging therapies in Australia.
- 5.134 One submitter mentioned being treated by the emerging therapy omalizumab (trade name Xolair), which was added to the PBS last year. Omalizumab is used to treat severe allergic asthma and is a monoclonal antibody therapy, similar to dupilumab. The author of the submission had previously been given the medication under compassionate supply from the manufacturer but has developed an allergy to the medication and can no longer take it. While they were able to take omalizumab, the author found it an excellent treatment.<sup>135</sup>
- 5.135 Another submitter noted they were pleased omalizumab had been added to the PBS. They stated ‘biologicals’ (drugs like omalizumab and dupilumab) are expensive for the Government to subsidize but are preferable to the long term side effects of the corticosteroids or chemotherapy drugs which are currently prescribed for severe allergic conditions.<sup>136</sup>
- 5.136 The biopharmaceutical company Sanofi stated that ‘identifying specific and effective biologic treatments continues to be an area of unmet need for patients.’<sup>137</sup> It has investigated a number of research strategies but has found that modifying immune dysregulation has been most successful.<sup>138</sup>
- 5.137 New technologies have also been developed for venom immunotherapy. Clinical trials are currently undergoing in South Australia and Tasmania by the Australian biotechnology company Vaxine Pty Ltd to see if the adjuvant Advax™ can increase the efficacy of current desensitisation therapies for ant

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<sup>134</sup> Department of Health, Pharmaceutical Benefits Scheme (PBS), *March 2020 PBAC Meeting – Positive Recommendations*, p. 5, <<https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2020-03/positive-recommendations-03-2020.pdf>> viewed 20 May 2020.

<sup>135</sup> Mr Nathan Pokoney, *Submission 104*, p. 11.

<sup>136</sup> Name withheld, *Submission 243*, p. 1.

<sup>137</sup> Sanofi, *Submission 204*, p. 10.

<sup>138</sup> Sanofi, *Submission 204*, p. 10.

bites and bee stings. This trial has struggled to attract funding from the NHMRC and other Australian funding agencies however.<sup>139</sup>

## Alternative medicines and therapies

- 5.138 The Committee received evidence about alternative medicines and therapies practiced by allergy patients. Alternative medicines or therapies, sometimes referred to as complementary medicines, are medical products containing ingredients such as vitamins, minerals, herbs, nutritional supplements, aromatherapy preparations and homeopathic medicine. These products are regulated in Australia under the *Therapeutic Goods Act 1989 (Cth)*.<sup>140</sup>
- 5.139 Therapeutic devices (defined as a device used to diagnose, prevent, monitor, treat or alleviate an injury, disease or disability) can be registered on the Australian Register of Therapeutic Goods (ARTG) in Australia if the company submits an application to the Therapeutic Goods Administration (TGA). Depending on the risk level of the device, the TGA may assess the application before registering the device on the ARTG.<sup>141</sup>
- 5.140 The TGA stated that it is aware of allergy testing devices which are not listed on the ARTG. These include Vega (electro-diagnosis) testing, Kinesiology, Iridology, VoiceBio, the Alcat, and Cytotoxic testing (Bryan's Test). There are also several allergy remedies available commercially based on 'tradition of use' such as traditional Chinese medicine, homeopathic remedies and aromatherapy.<sup>142</sup>
- 5.141 In order to prevent and address medical devices or medicines being inappropriately promoted to consumers (such as making claims of treating or curing allergies when there is no proof of this) the TGA has several measures in place. These include a complaints process, random or targeted post-market review, advertising requirements, and sanctions (e.g. directions, infringement notices, and civil or criminal penalties) for companies that continue with non-compliant advertising.<sup>143</sup>

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<sup>139</sup> Name withheld, *Submission 133*, p. 3.

<sup>140</sup> Department of Health, Therapeutic Goods Administration (TGA), 'An overview of the regulation of complementary medicines in Australia' <<https://www.tga.gov.au/overview-regulation-complementary-medicines-australia>> viewed 24 February 2020.

<sup>141</sup> DoH, *Submission 78.2*, Answer to Question on Notice, p. 2.

<sup>142</sup> DoH, *Submission 78.2*, Answer to Question on Notice, p. 2.

<sup>143</sup> DoH, *Submission 78.2*, Answer to Question on Notice, pp. 2-3.

- 5.142 Ms Loretta Marron, Chief Executive Officer of Friends of Science in Medicine, said that the use alternative therapies in the place of conventional medicine can harm patients in three ways: financial harm to the patient, harm to them from disappointment when the treatment doesn't work, and harm from the delay of diagnosis and proper treatment.<sup>144</sup>
- 5.143 The Department of Health noted that it 'is aware of a number of non-validated diagnostic and treatment approaches being used by some health practitioners to diagnose and manage allergies'.<sup>145</sup> If a health practitioner is found to be practicing medicine in an unsafe way there are regulatory measures, professional codes of conduct and associated compliance actions which protect the public.<sup>146</sup>
- 5.144 The NAS stated that allergy patients often seek alternative health practitioners in cases where there are delays in access to care or when treatment options are limited. The non-validated testing and treatment options offered by many alternative practitioners can be expensive as well as unsafe through the use of overly restrictive elimination diets.<sup>147</sup>
- 5.145 Dr Brynn Wainstein, President of ASCIA, said that use of alternative therapies can increase the costs and burdens to the Australian health care system:
- Incorrect diagnosis and management can lead to higher needs for patients once they do get access to an allergy specialist, requiring more appointments and lengthening waiting lists overall.<sup>148</sup>
- 5.146 Dr Wainstein said he is aware of many cases where the initial consultation between a patient and an allergy specialist is spent undoing harm from previously given incorrect advice and diagnosis. There are also cases of mild allergic disease, such as mild eczema or hay fever, which have been poorly treated and become serious ongoing problems requiring specialist treatment from an allergist or immunologist: 'The result of this is that inappropriate

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<sup>144</sup> Ms Loretta Marron, Chief Executive Officer, Friends of Science in Medicine, *Committee Hansard*, Brisbane, 18 February 2020, p. 47.

<sup>145</sup> DoH, *Submission 78*, p. 8.

<sup>146</sup> DoH, *Submission 78*, p. 8.

<sup>147</sup> NAS, *Submission 118*, p. 20.

<sup>148</sup> Dr Brynn Wainstein, President, Australasian Society of Clinical Immunology and Allergy (ASCIA), *Committee Hansard*, Sydney, 19 November 2019, p. 14.

healthcare encounters make the bottlenecks for access to allergy services worse rather than better.’<sup>149</sup>

- 5.147 Dr Preeti Joshi, Co-chair of the NAS, reinforced Dr Wainstein’s comments, saying that parents of children with severe allergies sometimes turn to alternative medicine due to long waiting times to see specialists. This is why organisations like NAS and ASCIA are looking into shared care models of medical practice, particularly in rural areas, in an attempt to alleviate long waiting times.<sup>150</sup>
- 5.148 Dr Joshi said further that there currently are alternative medical practices operating without any specialist input that claim to be ‘allergy centres’, charging patients large amounts of money for treatment. In some cases these clinics are staffed by GPs.<sup>151</sup>
- 5.149 Dr Emily Amos, a GP and parent of children with allergies, wrote that she understands the desperation of parents who seek alternative therapies for their severely allergic children, noting that ‘desperation will breed misinformation.’<sup>152</sup> She said that the remedy for this is better access to reliable and sympathetic information from reputable sources. She referenced ASICA’s website and factsheets, as well as the A&AA Facebook group as excellent sources of up to date information and support groups for parents of children with allergies.<sup>153</sup>
- 5.150 Dr Merryn Netting, a paediatric dietician specialising in allergy, wrote that consumers who seek alternative medical treatment are sometimes referred for non-validated food allergy testing, such as IgG<sup>154</sup> testing (as opposed to the standard IgE testing) which is expensive and often results in unnecessary food restrictions. She is particularly concerned about the use of broad exclusion diets in children as it may result in the development of more

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<sup>149</sup> Dr Wainstein, ASCIA, *Committee Hansard*, Sydney, 19 November 2019, p. 14.

<sup>150</sup> Dr Preeti Joshi, Co-Chair, National Allergy Strategy (NAS), *Committee Hansard*, Sydney, 19 November 2019, p. 16.

<sup>151</sup> Dr Joshi, NAS, *Committee Hansard*, Sydney, 19 November 2019, p. 16

<sup>152</sup> Dr Emily Amos, *Submission 15*, p. 4

<sup>153</sup> Dr Amos, *Submission 15*, p. 4.

<sup>154</sup> Immunoglobulin G (IgG). IgG is a blood test that may show food sensitivities and are subtler and can last longer than the traditional IgE allergy.

serious allergies and anaphylaxis and in some cases can lead to malnutrition.<sup>155</sup>

- 5.151 One submitter said that after their son started displaying allergy symptoms they were put on the waiting list, which was 18 months long, to see a public paediatric immunologist. Their GP would not provide skin prick testing to determine allergens so the family turned to a kinesiologist who used 'muscle impulse testing' to diagnose their son's allergies. The family also paid for IgG blood testing which showed their son was allergic to multiple foods. The family used this information as a guide until they were able to get reliable testing done through a specialist. The submitter stated however they are aware of many people who rely on IgG blood testing and eliminate food groups from their child's diet based on its results.<sup>156</sup>
- 5.152 A child care sector worker said they are aware of parents taking their children to companies which will provide diagnoses of allergies and supporting letters to them without any testing or follow up of the child's medical concerns. Parents are self-diagnosing their children and then finding a company that will provide documentation for the food they would like to exclude from their child's diet. The submission said there needs to be higher standards for companies providing medical testing to the public.<sup>157</sup>
- 5.153 The Allergy Medical Group noted that it has seen a growth of alternative practitioners offering kinesiology, vega testing, acupuncture, homeopathy and crystal therapy among others to treat allergies, usually costing patients between one and two thousand dollars per treatment. It was also aware of mainstream medical practitioners offering IgG testing despite it being 'useless in the context of allergy.'<sup>158</sup>
- 5.154 Professor Peter Smith, Director of the Allergy Medical Group, suggested that alternative practitioners who misrepresent their treatments should be pursued by health authorities.<sup>159</sup>
- 5.155 Professor Smith also said that part of the decision by a patient to seek alternative therapies was often due to waiting times to see medical

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<sup>155</sup> Dr Merryn Netting, *Submissions 222*, p. 4.

<sup>156</sup> Name withheld, *Submission 17*, p. 3.

<sup>157</sup> Name withheld, *Submission 19*, p. 3.

<sup>158</sup> Allergy Medical Group, *Submission 244*, p. 1.

<sup>159</sup> Prof Peter Smith, Allergist and Director, Allergy Medical Group, *Committee Hansard*, Brisbane, 18 February 2020, pp. 15-16.

specialists. 'If somebody has got a six to twelve or eighteen month wait, they're going to go and look elsewhere where people make promises to help them.'<sup>160</sup>

- 5.156 The ACN highlighted that misdiagnosis and over diagnosis of allergies is a significant problem in the community which often leads to unnecessary exclusion diets. They are aware of allergy testing being done through hair sample and blood tests by naturopaths and other alternative practitioners and the high costs charged by these providers.<sup>161</sup>
- 5.157 Another submitter stated that social media patient support forums on Facebook often have people promoting alternative medical treatment as well as special diets and foods for the treatment of allergies and eczema. Misinformation is also common, as well as people encouraging others to cease prescribed treatments such as cortisone creams. The author has also witnessed businesses promoting cosmetic products to allergy and eczema sufferers which have not been assessed by the TGA.<sup>162</sup>
- 5.158 This view was echoed by A&AA, stating that social media platforms like Facebook can be highly useful forums for support and for allergy sufferers to benefit from the experiences of others. However, if poorly managed these groups can be sources of misinformation which can lead to poor and even dangerous outcomes for followers.<sup>163</sup>
- 5.159 The ACN drew parallels between allergy patients seeking alternative therapies and the increasing phenomenon of vaccine hesitancy and rejection. They said:
- The World Health Organisation has found that decisions to refuse vaccination despite its availability are highly contextual and that health provider recommendations are effective in overcoming that hesitancy because health workers remain the most trusted advisor and influencer of vaccination decisions.<sup>164</sup>

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<sup>160</sup> Prof Smith, Allergy Medical Group, *Committee Hansard*, Brisbane, 18 February 2020, p. 16.

<sup>161</sup> ACN, *Submission 158*, p. 3.

<sup>162</sup> Name withheld, *Submission 82*, p. 3.

<sup>163</sup> A&AA, *Submission 184*, p. 23.

<sup>164</sup> ACN, *Submission 124*, p. 5.

- 5.160 The ACN wrote that increasing the involvement of nurses in allergy treatment and management would be a key strategy to reducing the uptake of alternative diagnosis and treatments.<sup>165</sup>
- 5.161 ausEE Inc. highlighted that sufferers of EGID and EoE may seek alternative treatments due to a lack of a reliable test that determines what foods may trigger their disease, as well as the limited availability of medications to treat their EOE. As well as this, due to the relative rarity of EoE and lack of knowledge about it amongst many medical practitioners, some EoE sufferers may resort to alternative therapies to manage their EoE symptoms which have not been identified by mainstream medicine. ausEE Inc. states that some of their members have found alternative therapies beneficial while other have found the treatments expensive and the advice conflicting and in some cases even dangerous.<sup>166</sup>
- 5.162 Ms Amanda Lennestaal, a parent of a child with FPIES, wrote in her submission that parents of children with FPIES sometimes seek treatment outside of mainstream medicine. She said that although many children outgrow FPIES, the stress and difficulty of caring for a child with this condition makes many parents susceptible to alternative treatments that promise a cure. She knows of parents who have spent large amounts of money on iridology, skin prick testing and hair analysis in order to diagnose their child. Others have turned to essential oils or nutrition products sold through direct sales methods. Many turn to these methods due to the lack of care they have received in the public healthcare system.<sup>167</sup>
- 5.163 Coeliac Australia wrote that self-diagnosis and alternative therapies used without mainstream testing and oversight are a problem in Australia. The prevalence of coeliac disease in Australia is approximately 1.4 per cent; however studies from the CSIRO in 2016 found that 12.1 per cent of Australians avoid wheat and/or gluten. This not only results in an unnecessarily restricted diet but adds to the perception that gluten intolerance is a lifestyle choice rather than a serious medical condition.<sup>168</sup>
- 5.164 The Committee received submissions from allergy sufferers who are using alternative treatments. One submission from a woman suffering from mammalian meat allergy said she is seeing a naturopath as there were no

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<sup>165</sup> ACN, *Submission 124*, p. 5.

<sup>166</sup> ausEE Inc., *Submission 168*, pp. 10-11.

<sup>167</sup> Ms Amanda Lennestaal, *Submission 242*, p. 2.

<sup>168</sup> Coeliac Australia, *Submission 132*, p. 4.

other options for treatment and she is on a waiting list to get into a clinic.<sup>169</sup> Another submission said they would trial kinesiology for their child and that they 'have seen energy work assist others with allergies.'<sup>170</sup>

- 5.165 The Friends of Science in Medicine, a group that supports evidence-based medicine, noted that there are many natural therapies using 'biofeedback' or 'electro-diagnosis' devices which are listed with the TGA, despite having little scientific evidence to back their claims. Some of these devices claim to assist in the treatment of allergies and anaphylaxis.<sup>171</sup>
- 5.166 The TGA reviewed bio-resonance and bio-feedback devices in order to verify these devices' therapeutic claims were supported by scientific evidence. This led to the cancellation of 15 devices from the ARTG, either through sponsors withdrawing their support for the device or by the TGA itself.<sup>172</sup>
- 5.167 The removal of devices from the ARTG does not however prevent practitioners from selling these devices or using them during patient consultations as long as they do not make claims regarding these devices' therapeutic efficacy.<sup>173</sup>
- 5.168 The TGA also stated that it 'intends to escalate its regulatory response where necessary to address ongoing noncompliant advertising. This may include the use of official warnings, directions notices and infringement notices as appropriate.'<sup>174</sup>

### **Committee comment**

- 5.169 The Committee is pleased to see the research being done by CFAR, hospitals, universities, and other research organisations and notes the cutting edge research being done in the area of allergies. Despite this, the Committee is concerned that the NHMRC did not award any specific funding for allergy related research in the 2019 funding round and that there has not been a significant increase in allergy funding since 2015. It is also concerned that the funding for CFAR does not extend past 2022.

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<sup>169</sup> Name withheld, *Submission 221*, pp. 1-2.

<sup>170</sup> Ms Amy Marley, *Submission 60*, p. 8.

<sup>171</sup> Friends of Science in Medicine, *Submission 61*, p. 1.

<sup>172</sup> DoH, *Submission 78.2*, Answer to Question on Notice, p. 5.

<sup>173</sup> DoH, *Submission 78.2*, Answer to Question on Notice, p. 5.

<sup>174</sup> DoH, *Submission 78.2*, Answer to Question on Notice, p. 5

- 5.170 The presence of a placebo in clinical and research trials can be a disincentive, particularly to parents who are considering placing their children in research trials. The Committee shares these concerns and would like to see a larger number of trials offered which have no placebo, similar to the model used for vaccine trials.
- 5.171 The Committee believes there is merit in funding clinical allergen trials into allergens other than peanut allergy in Australia.
- 5.172 The Committee also suggests that ASCIA promote currently available trials on their website to ensure there is public knowledge of current trials.
- 5.173 The Committee was very interested in the large amount of evidence it received about food based oral immunotherapy. It was concerned by the amount of people who are going to the United States of America and elsewhere to receive this treatment, often at great personal and financial expense.
- 5.174 The Committee notes that there is a large gap between the experiences of people who have undergone food based OIT overseas and the views of the Australian medical specialist community who would like there to be more study of this therapy before any sort of clinical roll-out. The Committee recognises and appreciates the views of both sides in this issue; the frustration of parents of allergic children whose lives are highly affected by these allergies and the desire of the scientific community for evidence-based research and the absolute priority of patient safety and efficacy.
- 5.175 The Committee is particularly concerned about the current generation of children with severe allergy as they enter adolescence, a time when young people are exposed to new, less controllable environments, when there is less parental supervision, and when people are more likely to engage in risk taking behaviour.
- 5.176 Despite this, the Committee is also aware that OIT is a relatively new treatment and there are still many unknowns about this therapy. The Committee would like to see research undertaken into the long term prognosis of people who have undergone OIT and the chances of remission for allergy sufferers. It would also like to see research done into side effects of OIT, such as the risk of developing eosinophilic oesophagitis or anaphylaxis during treatment.
- 5.177 On a more practical level, the Committee is also concerned by how a rollout of OIT would be facilitated in Australia and how this would impact on existing allergy and immunology services with current high demand and

long waiting lists. The Committee has received evidence throughout the inquiry about long waiting times to see allergists and immunologists for initial appointments as well as for existing allergy treatments such as food challenges. Although some people giving evidence believed OIT could be rolled out through clinical hospital based practice, the Committee is not convinced this is realistic or practical due to workforce and funding issues.

- 5.178 The Committee received numerous submissions requesting that the new biological therapy dupilumab be listed on the PBS and was very moved by the suffering of people who live with severe eczema.
- 5.179 The Committee was pleased to find out that the PBAC had decided to recommend dupilumab for listing on the PBS in its March 2020 meeting.
- 5.180 There is clear evidence that people who suffer from allergies and anaphylaxis and other allergic diseases such as eczema or allergic rhinitis are particularly susceptible to the promises of alternative therapy providers due to long waiting times to see allergy specialists and the often limited nature of treatments available.
- 5.181 The Committee sympathises with people who seek alternative treatments, especially those who feel they have no other choice due to long waiting times or a lack of understanding from practitioners who may be unfamiliar with rarer allergenic diseases such as eosinophilic oesophagitis or FPIES. The Committee also recognises that alternative medicine and therapies can play a role in health care when used alongside conventional medicine.
- 5.182 Despite this, the Committee is very concerned by the proliferation of unscientific cures and advice on social media platforms in particular, as well as the proliferation of IgG allergy testing offered by alternative practitioners which can have limited diagnostic validity.
- 5.183 The exclusive use of alternative therapies can lead to more pressure on existing resources when people do see an allergy specialist as patients who have previously seen alternative practitioners can have higher needs, require more education, or may have conditions exacerbated by postponing conventional treatments.
- 5.184 The Committee agrees with the Australian College of Nurses that an increased role of nurses in allergy care, particularly in cases where access to specialists is limited, may assist in reducing uptake of alternative therapies.
- 5.185 The Committee was pleased to hear that 15 bio-resonance devices had been de-listed from the ARTG though is concerned about the proliferation of similar non-scientific therapeutics which still exist on the market.

### **Recommendation 23**

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- 5.186** The Committee recommends that the Australian Government give consideration of how best to increase the utilisation of nurses and allied health care workers to support the care of patients with allergic disease.

### **Recommendation 24**

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- 5.187** The Committee recommends that the Therapeutic Goods Administration and any other relevant authorities, such as the Australian Competition and Consumer Commission (ACCC) conduct an independent, evidence-based review into all therapeutic goods, services, or devices which claim to diagnose or treat allergies.

## A. List of submissions

- 1 *Name Withheld*
- 2 Mrs Catherine Bryant
- 3 Miss Juliana Byers
- 4 Dr Louise Burns
- 5 *Name Withheld*
- 6 Joanne Hagiliassis
- 7 *Name Withheld*
- 8 *Name Withheld*
- 9 Ms Nikki Brown
- 10 *Name Withheld*
- 11 *Name Withheld*
- 12 *Name Withheld*
- 13 *Name Withheld*
- 14 Sandy and Jason Pace
- 15 Dr Emily Amos
- 16 Miss Jenna Nelson
- 17 *Name Withheld*
- 18 Ms Maria Stipic
- 19 *Name Withheld*
- 20 Ms Sally Clark

- 21 *Name Withheld*
- 22 *Name Withheld*
- 23 Ms Patty Delaney
- 24 *Name Withheld*
- 25 Mrs Samantha Mills
- 26 *Name Withheld*
- 27 *Name Withheld*
- 28 Dr Robyn Stephenson
- 29 Mr Craig Blinco
- 30 Purifi Air Purification
- 31 Mrs Ann Klarich
- 32 Dr mercedez Hinchcliff
- 33 David Campbell
- 34 *Name Withheld*
- 35 Mrs Linda Norwood
- 36 Dr Suzan Bekir
- 37 Mrs Simone Albert
- 38 *Name Withheld*
- 39 Ms M Post
- 40 *Name Withheld*
- 41 Dietary Hawk
- 42 *Name Withheld*
- 43 *Name Withheld*
- 44 *Name Withheld*
- 45 Australasian College of Dermatologists
- 46 *Name Withheld*
- 47 Food Allergy Goals
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- 48 *Name Withheld*

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- 49 *Name Withheld*
- 50 A/Prof Michael Sladden
- 51 *Name Withheld*
- 52 *Name Withheld*
- 53 *Name Withheld*
- 54 Global Anaphylaxis Awareness and Inclusivity - globalaaai
- 55 *Name Withheld*
- 56 *Name Withheld*
- 57 *Name Withheld*
- 58 *Name Withheld*
- 59 Ms Helen Marrero
- 60 Ms Amy Marley
- 61 Friends of Science in Medicine
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- 62 Mrs Margaret Magele
- 63 *Name Withheld*
- 64 Jana Pearce
- 65 Jo-anne Hickey
- 66 *Name Withheld*
- 67 Ms Sue Williams
- 68 Mrs Catherine Sly
- 69 Pharmaceutical Society of Australia
- 70 Ms Doreen Denny
- 71 *Name Withheld*
- 72 Simon Tate and Gabrielle Catan
- 73 *Name Withheld*
- 74 *Name Withheld*
- 75 *Name Withheld*
- 76 Dr Peter Bourke

- 77 *Name Withheld*
- 78 Department of Health
- 78.1 Supplementary to submission 78
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- 79 *Name Withheld*
- 80 *Name Withheld*
- 81 *Name Withheld*
- 82 *Name Withheld*
- 83 Prof Dominic Mallon
- 84 Australian Paediatric Society
- 84.1 Supplementary to submission 84
- 85 Make Australia Healthy Again
- 86 *Name Withheld*
- 87 *Name Withheld*
- 88 Mrs Kym Banjac
- 89 Ms Jenny Murtagh
- 90 Mrs Teresa Nielsen
- 91 *Name Withheld*
- 92 My Food Allergy Friends
- 93 *Name Withheld*
- 94 *Name Withheld*
- 95 *Name Withheld*
- 96 Edith Cowan University
- 97 Centre for Food & Allergy Research (CFAR)
- 98 *Name Withheld*
- 99 *Name Withheld*
- 100 *Name Withheld*
- 101 Mrs Sarah Dubravica
- 102 *Name Withheld*

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- 103 *Name Withheld*
- 104 Mr Nathan Pokoney
- 105 *Name Withheld*
- 106 *Name Withheld*
- 107 *Name Withheld*
- 108 *Name Withheld*
- 109 Allergy Support Hub
- 110 *Name Withheld*
- 111 Ms Madeleine Sy
- 112 Tourism Accommodation Australia
- 113 *Name Withheld*
- 114 *Name Withheld*
- 115 Australian Vaccination-risks Network Inc.
- 116 ANZAAG
- 117 *Name Withheld*
- 118 National Allergy Strategy
- 119 *Name Withheld*
- 120 *Name Withheld*
- 121 *Name Withheld*
- 122 Mr Shaymaviswanathan Karnaneedi
- 123 *Name Withheld*
- 124 Australian College of Nursing
- 125 Dr Sara Barnes
- 126 NSW Anaphylaxis Education Program
- 127 Australian Food and Grocery Council
- 128 *Name Withheld*
- 129 Carly Morton and Graham Pidco
- 130 Mrs Elise Short
- 131 *Name Withheld*

- 132 Coeliac Australia
- 133 *Name Withheld*
- 134 *Name Withheld*
- 135 Mrs Sally Pokoney
- 136 *Name Withheld*
- 137 TiARA (Tick-induced Allergies Research and Awareness)
- 138 Consumer Healthcare Products (CHP) Australia
- 139 Norma Greeff
- 140 Immunology Department, Royal Adelaide Hospital
- 141 Maurice Blackburn Lawyers
- 141.1 Supplementary to submission 141
- 142 *Name Withheld*
- 143 *Name Withheld*
- 144 Mr James Norton
- 145 Allergen Bureau
- 146 *Name Withheld*
- 147 Mr Stephen & Rebecca Roberts
- 148 *Name Withheld*
- 149 Australian Institute of Food Science and Technology
- 150 *Name Withheld*
- 151 *Name Withheld*
- 152 *Name Withheld*
- 153 ASCIA (Australasian Society of Clinical Immunology and Allergy)
- 154 Mrs Carolina Valerio
- 155 Dr Nick Cooling, Mr Malcolm Turner, Dr Troy Wanandy and Ms Jenny Gudden
- 156 *Name Withheld*
- 157 *Name Withheld*
- 158 Australian College of Nurse Practitioners

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- 159 Mrs Judith McCrea
- 160 Queensland University of Technology
- 161 *Name Withheld*
- 162 *Name Withheld*
- 164 *Name Withheld*
- 165 *Name Withheld*
- 166 Society of Hospital Pharmacists of Australia
- 167 *Name Withheld*
- 168 ausEE Inc
- 169 Jack Jumper Allergy Program
- 170 *Name Withheld*
- 171 *Name Withheld*
- 172 Eczema SUPPORT Australia Ltd
- 173 Food Standards Australia New Zealand
- 174 Mrs Kirsty Russell
- 175 Dr Prathyusha Sanagavarapu
- 176 Freedom Foods Group Limited
- 177 *Name Withheld*
- 178 *Name Withheld*
- 179 A L Hutton
- 180 *Name Withheld*
- 181 *Name Withheld*
- 182 Child and Adolescent Health Service
- 183 Ms Carly Morton
- 184 Allergy & Anaphylaxis Australia
- 185 *Name Withheld*
- 186 Debra Pidco
- 187 Adelaide Hills Community Jumping Jack/Hopper Ant Action Group
- 188 Mrs Alex Argenio

- 189 *Name Withheld*
- 190 Ms Ciara Paramore
- 191 *Name Withheld*
- 192 *Name Withheld*
- 193 *Name Withheld*
- 194 Mrs Cindy Egan
- 195 Mrs Monique Boatwright
- 196 *Name Withheld*
- 197 Pourus Bharucha
- 198 Miss Courtney Ward
- 199 *Name Withheld*
- 200 *Name Withheld*
- 201 Suesan Cox
- 202 *Name Withheld*
- 203 *Name Withheld*
- 204 Sanofi
- 205 Dr Raymond Mullins
- 206 Dr Richard Loh
- 207 Dr Sebastian Cordoba BSW (Hons), PhD, Victoria Butler and Leon Cordoba
- 208 Campbelltown Hospital
- 209 Mrs Joy Cowdery
- 210 *Name Withheld*
- 211 Mrs Vicki Nikolovska-Wright
- 212 Ms Emily Marney
- 213 *Name Withheld*
- 214 Mr Vincent Lam
- 215 Migraine Australia
- 216 *Name Withheld*
- 217 DR JOHN PIESSE

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- 218 *Name Withheld*
- 219 Dr Giovanni Zurzolo
- 220 *Name Withheld*
- 221 *Name Withheld*
- 222 Dr Merryn Netting
- 223 *Name Withheld*
- 224 Dr Michelle Warton
- 225 Mrs Elizabeth Boyle
- 226 *Name Withheld*
- 227 *Name Withheld*
- 228 Skills Impact
- 229 Restaurant and Catering Industry Association
- 230 Asthma Australia
- 231 *Name Withheld*
- 232 *Name Withheld*
- 233 *Name Withheld*
- 234 Dr Paxton Loke
- 235 Australian Allergy Immunology Specialists in Private Practice
- 236 Food and Controlled Drugs Branch, SA Health
- 237 MACCS Medical Group
- 238 Stallergenes Greer
- 239 Dr Ana Dosen
- 240 Mr Leigh Marten
- 241 *Name Withheld*
- 242 Ms Amanda Lennestaal
- 243 *Name Withheld*
- 244 *Confidential*
- 245 *Name Withheld*
- 246 *Name Withheld*

- 247 Ms Carolyn Fitzgibbon
- 248 Ms Connie Crawford
- 249 MS Maureen MINCHIN
- 250 Mandy and Francis Hogan
- 251 Mrs Rebecca Sertori
- 252 Ms Kylie Jacobsen
- 253 Department of Industry, Innovation and Science
- 254 Dr Adriana Le
- 255 Women's and Children's Health Network (WCHN)
- 256 Gerrard Twomey
- 257 Department of Agriculture, Water and the Environment

## **B. Exhibits**

- 1     Gerrard Twomey, Part 1 (Submission 256)
- 2     Gerrard Twomey, Part 2 (Submission 256)
- 3     Gerrard Twomey, Part 3 (Submission 256)
- 4     Gerrard Twomey, Part 4 (Submission 256)
- 5     Gerrard Twomey, Part 5 (Submission 256)



# C. Hearings and Witnesses

## **Thursday, 24 October 2019 - Canberra**

*Department of Health*

- Dr Lisa Studdert, Deputy Secretary
- Professor Brendan Murphy, Chief Medical Officer

## **Monday, 18 November 2019 - Melbourne**

*Mrs Simone Albert, Private capacity*

*Mrs Jody Clooney, Private capacity*

*Dr Emily Amos, Private capacity*

*Mrs Suzanne Parry, Private capacity*

*Ms Jenny Murtagh, Private capacity*

*Ms Maria Stipic, Private capacity*

*Mrs Linda Norwood, Private capacity*

*Department of Allergy and Immunology, Royal Children's Hospital*

- Dr Joanne Smart, Director

*Royal Melbourne Hospital*

- Prof Jo Douglass, Head, Department of Clinical Immunology and Allergy

*Monash University/Alfred Health*

- Prof Robyn O'Hehir AO

*Alfred Health*

- Prof Mark Hew, Head of Allergy, Asthma and Clinical Immunology Services

*Dr Kirsten Perrett, Private capacity*

*Dr Catherine Hornung, Private capacity*

*Dr Rachel Peters, Private capacity*

*Dr Giovanni Zurzolo, Private capacity*

*Ms Victoria Soriano, Private capacity*

*Anaphylaxis Network Australia*

- Mrs Joanne Hagiliassis

*Maurice Blackburn Lawyers*

- Mr Barry Hickey
- Mr Peter Newling
- Ms Dimi Ioannou

*Dr Rebecca Werther (private allergist), Private capacity*

*Food Allergy Goals*

- Ms Melissa Mooney
- Ms Simone Albert

*Dr Dean Tey, Private capacity*

*Australian Paediatrics Society*

- Dr Peter Goss

*Ms Helen Marrero, Private capacity*

**Tuesday, 19 November 2019 - Sydney**

*Miss Ashley Wong and Mrs Karen Wong, Private capacity*

*Mrs Chelsea Taylor, Private capacity*

*Mrs Carolina Valerio, Private capacity*

*Ms Eloise Roelandts, Private capacity*

*Dr Prathyusha Sanagaovarapu, Private capacity*

*Australasian Society of Clinical Immunology and Allergy (ASCIA)*

- Ms Jill Smith, CEO
- Dr Brynn Wainstein, President

*National Allergy Strategy*

- Ms Sandra Vale, National Allergy Strategy Manager
- Dr Preeti Joshi, Co-Chair
- Ms Maria Said, Co-Chair

*Westmead Children's Hospital*

- Dr Melanie Wong

*Allergy and Anaphylaxis Australia*

- Ms Maria Said, CEO
- Mrs Jody Aiken, Health Management Educator
- Mrs Karen Wong, Operations Manager

*TiARA*

- Prof Sheryl van Nunen
- Prof Nicholas Cowdery AO
- Prof Tony Basten AO

*Australasian College of Dermatologists*

- Dr Joseph Konya, Fellow

*Campbelltown Hospital/Western Sydney Uni*

- Prof Constance Katelaris AM

*NSW Anaphylaxis Education Program*

- Mrs Briony Tyquin
- Dr Lara Ford

*Australian Institute of Food Science and Technology*

- Mrs Fiona Fleming, Managing Director

*Australian Food and Grocery Council Australia*

- Dr Geoffrey Annison, Deputy CEO
- Ms Kim Tonnet, Regulatory Manager, Scientific and Technical

*Australian Allergy Centre*

- Dr Suzan Bekir

## **Thursday, 6 February 2020 - Canberra**

*Food Standards Australia New Zealand*

- Mr Mark Booth, Chief Executive Officer
- Mr Derek Castles, Project Officer
- Ms Jenny Hazelton, Labelling and Information Standards

## **Thursday, 13 February 2020 - Canberra**

*Department of Health*

- Dr John Skerritt, Deputy Secretary
- Dr Jane Cook, First Assistant Secretary, Medicines Regulation

## **Monday, 17 February 2020 - Adelaide**

*Roundtable - personal stories*

- Ms Fiona Cheminant
- Mrs Sarah Dubravica
- Mrs Alex Argenio

*Allergy specialists panel - Department of Allergy and Clinical Immunology, The Women's and Children's Hospital*

- Ms Liz Forsyth, Adelaide Hills Community Jumping Jack/Hopper Ant Action Group
- Dr Adriana Le, Royal Adelaide Hospital
- Dr Pravin Hissaria, Royal Adelaide Hospital
- Ms Jenny Gudden, Royal Hobart Hospital
- Mr John Alexandrou, Pharmacist and community member

*Dietary Hawk*

- Mr Themis Chryssidis, Managing Director

*Global Anaphylaxis Awareness and Inclusivity (Globalaai)*

- Dr Pooja Newman, Founder

*Allergy Support Hub - via teleconference*

- Ms Monique Kerr, Psychologist
- Ms Bethany Ward, Psychologist

*Ms Carly Morton, Private capacity*

*Edith Cowan University - via teleconference*

- Professor Amanda Devine
- Ms Rosalind Sambell, Lecturer
- Dr Ruth Wallace, Academic Researcher

*Associate Professor Richard Loh, WA Child Adolescent Health Services - via teleconference*

## **Tuesday, 18 February 2020 - Brisbane**

*Roundtable - personal stories*

- Mrs Teresa Nielsen
- Ms Marketta Culley
- Mrs Catherine Sly

*Medical Professionals*

- Professor Peter Smith, Director, Allergy Medical Group
- Dr Birgit Marchand, Paediatric Allergist and Immunologist, Queensland Allergy Service
- Ms Jody Thompson, Nurse Practitioner, Allergy Medical Group

*ausEE Inc*

- Mrs Sarah Gray, President and Founder
- Ms Bella Gray, Member

*Eczema Support Australia*

- Ms Melanie Funk, Managing Director

*Queensland University of Technology*

- Professor Janet Davies, Head, Allergy Research Group, School of Biomedical Sciences and Institute of Health and Biomedical Innovation

*Australia and New Zealand Anaesthetic Allergy Group (ANZAAG)*

- Mr Richard Scolaro

*Australian Society of Anaesthetists*

- Dr Andrew Mulcahy
- Ms Jacintha Victor John, Policy Manager

*The Allergen Bureau*

- Ms Jasmine Lacis-Lee, Secretary and Director
- Ms Kirsten Grinter, President and Director

*Friends of Science in Medicine*

- Ms Loretta Marron, Chief Executive Officer

*Migraine Australia*

- Ms Raphaella Crosby, Founder and Chair of the Organising Committee

*My Food Allergy Friends - via teleconference*

- Ms Jacqueline Nevard, Founder