Australian Government

Australian Government response to the House of Representatives Standing Committee on Health, Aged Care and Sport report:

Walking the allergy tightrope – Addressing the rise of allergies and anaphylaxis in Australia

APRIL 2023

Overview

In August 2019, the issue of allergies and anaphylaxis in Australia was referred to the House of Representatives Standing Committee on Health, Aged Care and Sport (Committee) by the previous Government.

Australia has one of the highest rates of allergies in the world, affecting millions of children and adults. The Australian Government acknowledges there is currently no cure for allergies and daily life can be stressful and challenging for people with allergies and their families trying to avoid triggers and manage their symptoms. The Government therefore welcomes the Committee's report and its recommendations to improve diagnosis, treatment and support for allergy sufferers in a nationally consistent manner.

The Government would like to thank all of those involved in the Inquiry, including people with allergy and their families who outlined their personal experiences at the public hearings.

The Committee's report highlights issues with access to allergy specialists and treatments, inadequate allergy education for health professionals, underreporting of anaphylaxis, confusing food labelling, lack of drug allergy de-labelling programs, use of alternative and/or unproven treatments, to name a few.

The Government recognises the importance of ensuring health professionals and education providers have access to suitable allergies education and training, and for sufferers of allergic disease to have access to appropriate support, diagnosis and treatment options. The Government is committed to pursuing a nationally consistent approach to managing allergies and anaphylaxis and will encourage jurisdictions to act on recommendations to achieve this in the delivery of allergy services, education and training, and reporting.

The Australian Government Response supports (or supports in principle) 11 of the 24 recommendations. One response is noted, and the remaining 12 recommendations are partially supported. The Government already has arrangements in place to address some of the recommendations.

Some recommendations have financial implications which need to be considered in context with the Government's other competing budget priorities. Therefore, in principle support does not represent a commitment to funding.

The Committee's report highlights the roles of both the jurisdictions and the Australian Government in addressing the issues of allergies and anaphylaxis in Australia. Some of the recommendations do not fall within the remit of the Australian Government. In principle support for these recommendations indicates agreement with the benefits of these recommendations but recognises that the State and Territory governments are responsible for their funding and implementation.

Recommendations 1 and 2

1: 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.

2: 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.*

Partially supported

The Government recognises the value of a consistent approach to allergy management in Australia to ensure all Australians can access the best care available. The Government is providing funding of $16.6 million from 2022-23 to 2025-26 to the Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia (A&AA) to establish a National Allergy Council. This will ensure a nationally coordinated approach for the implementation of the National Allergy Strategy. The National Allergy Council will focus on:

- preventing allergic disease by expanding National Allergy Strategy programs, developing new programs based on research findings, and scoping the requirements for a national allergy reporting system;
- upskilling health professionals by expanding existing training resources and developing new models of training delivery;
- scoping the minimum requirements for potential inclusion of allergy training in the curriculum for health and education degrees;
- expanding existing, and developing new, online resources to support schools and early childhood education and care (ECEC) to implement the minimum standards for anaphylaxis prevention and management;
- providing support and advocacy for sufferers of allergic disease via A&AA;
- expanding and promoting food allergen management training in food service;
- expanding drug allergy education resources for health professionals, developing consumer information and standardising terminology in My Health Record for adverse drug reactions; and

- expanding the 250K youth project for young people with severe allergies.

The Government is also providing $10.2 million from 2022-23 to 2025-26 to the Murdoch Children's Research Institute to expand its Centre for Food and Allergy Research into a National Allergy Centre of Excellence. This will support a national collaboration of researchers and clinicians by centralising research on food, drug, vaccine, insect, and respiratory allergies. The National Allergy Centre of Excellence will:

- oversee a Clinical Trials Network that supports large scale studies embedded in routine clinical care, including for food allergy oral immunotherapy, penicillin de-labelling, venom immunotherapy for insect anaphylaxis, and respiratory allergy;
- establish a National Allergy Repository to collect and analyse data and biospecimens from Australian adults and children living with allergy across allergy domains;
- lead a series of living systematic reviews and stakeholder roundtables to synthesise and translate evidence for drug, food, insect and respiratory allergic diseases; and
- support, train and mentor the next generation of allergy researchers through competitive scholarships and fellowships in the field of allergy.

The National Health and Medical Research Council (NHMRC) is the government's lead agency for funding health and medical research. From 2012 to 2021, NHMRC has expended funding of over $105 million for research related to allergies and anaphylaxis, with $40 million in funding provided for food allergy research. In addition to this, $2.5 million was committed to the research grant 'Towards eradicating food allergy: from population to precision prevention, early intervention and management' for the Murdoch Children's Research Institute in 2022. NHMRC continues to welcome food allergy and anaphylaxis-related research grant applications from researchers through its standard research-funding mechanisms.

To complement its standard schemes, NHMRC sets aside annually a small proportion of its total expenditure budget to fund research through its Targeted Calls for Research (TCR) program. A TCR is a specific funding mechanism that seeks to greatly advance research or address a known gap in a particular area of health and medical science that will benefit the health of all Australians. NHMRC will continue to consider and prioritise new TCR topic proposals submitted by community and professional groups, as well as from states, territories and the Australian Government, in accordance with established processes.

In September 2019, the previous Government sought agreement through the former Australian Health Ministers' Advisory Council to work towards ensuring a nationally-aligned approach to notifications of anaphylactic episodes and death, and to engage with the National Allergy Strategy on the development of a national scheme (e.g. a national register). This was not agreed as it was a priority for all states and territories at the time or they required more information about how it would operate before engaging. Funding will be provided to the National Allergy Council to determine an appropriate anaphylaxis reporting

system and to scope its requirements, including determining legislative requirements/restrictions across different jurisdictions.

Recommendation 3

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.

Partially supported

Provisions already exist that enable some children or adults with severe and chronic allergic conditions to qualify for a Health Care Card (HCC) and/or Carer Allowance for their carers, where appropriate. Access is targeted based on need through means testing and qualification criteria that consider the severity of the condition and the level of care required. Providing access to Carer Allowance and/or a HCC solely based on a person's medical condition would mean that some people would receive public support even though they are financially able to meet their own costs and/or manage their own care needs.

HCCs are given to social security allowance payment recipients, or people who are on a low income. They provide access to Commonwealth Government health concessions, including a lower annual threshold to qualify for increased Medicare Benefits Schedule (MBS) benefits under the Extended Medicare Safety Net and cheaper co-payments for medicines listed on the Pharmaceutical Benefits Scheme (PBS).

Carer Allowance is designed to assist carers who provide a certain level of daily care and attention to a child or an adult who has a disability or medical condition. Qualification is based on the level of personal care that it is considered, or established, the carer provides. Carers who provide a qualifying level of care can qualify for Carer Allowance, regardless of the disability or medical condition of the care receiver.

An adult with chronic allergic conditions or anaphylaxis would generally be able to monitor and manage their environment to minimise any impact on their condition, and seek assistance when necessary. These actions are unlikely to require the level of personal care support that would qualify a carer for Carer Allowance.

Allergy sufferers with significant out-of-pocket costs may qualify for the MBS and PBS safety nets. For MBS services, the most significant safety net is the Extended Medicare Safety Net. Once an individual or family reach an annual threshold in out-of-hospital out-of-pocket spending, they may qualify for the Extended Medicare Safety Net which provides an increase in MBS benefits (generally up to 80% of out-of-pocket costs) for the remainder of the calendar year. The annual threshold for concession card holders and families eligible for Family Tax Benefit Part A is significantly lower than the annual threshold for all other individuals and families eligible for Medicare. All out-of-hospital out-of-pocket costs (the difference between the MBS out-of-hospital rebate and the practitioner's fee) contribute

towards reaching the EMSN thresholds. The PBS safety net limits the total annual cost of PBS medicines for families and individuals who require a large number of prescriptions. When a patient reaches the safety net threshold within a calendar year, they qualify to receive PBS items at a cheaper price or free of charge for the rest of that calendar year.

Recommendation 4

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 Allergy & Anaphylaxis Australia (A&AA).*

Supported in principle

With the support of all Australian governments, the Australian Commission on Safety and Quality in Health Care (Commission) has developed a national Acute Anaphylaxis Clinical Care Standard to improve the recognition of acute anaphylaxis and the provision of appropriate treatment and follow-up care. The standard was developed by a Topic Working Group which included representatives from key professional and consumer organisations and individual clinical experts. Following public consultation, the clinical care standard was finalised through the Commission's governance processes in June 2021 and launched on 24 November 2021. The standard has been endorsed by 15 key professional and consumer organisations, all state and territory health departments and the Australian Government Department of Health and Aged Care.

The Commission's Acute Anaphylaxis Clinical Care Standard identifies the components of care where the need for quality improvement is greatest, including prompt recognition and treatment of anaphylaxis, and discharge management. Discharge management should ensure that before a patient leaves a health care facility following anaphylaxis they receive:

- education about how to respond appropriately to a subsequent severe allergic reaction;
- an ASCIA Action plan;

- prescription or supply of up to two adrenaline auto-injectors if recommended in their circumstances, or advice to see their GP for a prescription as soon as possible where an autoinjector or prescription cannot be supplied before discharge; and
- arrangements for a prompt clinical immunology or allergy specialist consultation.

The Commission has developed a Discharge Checklist and Discussion Guide (the Checklist) as part of the suite of resources that support the clinical care standard. The Checklist is designed to ensure that discharge management provides the components of care required before discharge from the acute care setting and a clear pathway for follow-up care after discharge. The Checklist provides prompts for both the patient and their treating clinicians and includes information about where to seek support and advice for managing allergy and avoiding anaphylaxis.

The Acute Anaphylaxis Clinical Care Standard is based on a review of the existing guidelines and relevant literature, including the ASCIA guideline Acute Management of Anaphylaxis (2020) and the Safer Care Victoria Anaphylaxis Clinical Care Standard (2019).

According to the Safer Care Victoria Anaphylaxis Clinical Care Standard, patients should be discharged from an emergency department after an anaphylactic reaction with a prescription for two PBS-subsidised adrenaline injectors (EpiPens, Anapen or similar adrenaline injector devices) along with national resources developed by ASCIA and A&AA. The Safer Care Victoria Anaphylaxis clinical care standard also stipulates a specialist referral appointment be made for all patients who have experienced anaphylaxis, where possible prior to discharge. It is recommended that patients attend an appointment with their local general practitioner within five days after an anaphylactic event.

The arrangement described in the Safer Care Victoria Clinical Care Standard for emergency department prescription of PBS subsidised adrenaline injectors varies between states and territories and whether they participate in the PBS Reforms Agreement. PBS prescriptions are unavailable in NSW and the ACT hospitals. Consequently, not all patients will have access to an adrenaline injector on discharge unless the hospital dispenses one, the patient visits a general practitioner to receive an authority script immediately post-discharge, or purchases an injector privately from a pharmacy.

The PBS does not subsidise more than two adrenaline injectors at a time, however additional adrenaline injectors can be purchased privately from pharmacies without prescriptions. Further to this, a 500 microgram dose formulation of adrenaline injector (brand name Anapen) was listed on the PBS in September 2021, which can deliver higher single doses than previously available. This may reduce the number of injectors that may be needed by individuals who may otherwise have required 2 x 300 microgram adrenaline injectors to achieve an appropriate dose for their body weight.

Recommendation 5

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.*

Supported

The Australian Government values its partnership with ASCIA through the National Allergy Strategy and provides funding to implement actions of the strategy.

The Australian Government appreciates ASCIA's commitment to making quality allergy training available to health professionals. ASCIA's allergy and anaphylaxis educational resources and online e-training courses provide accessible, consistent and evidence-based education and training about prevention, recognition, diagnosis, treatment and management of allergies and anaphylaxis. The provision of standardised evidence-based training reduces the likelihood of inappropriately trained people providing allergy advice and treatment. The new funding of $16.6 million for the National Allergy Council includes funding to scope the minimum requirements for including allergy in the curriculum for medical and education degrees. It also includes funding to continue to upskill health professionals by providing and expanding existing training resources and developing new models of training delivery, particularly for regional, rural and remote health professionals to improve access to quality care.

Recommendation 6

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.

Partially supported

Telehealth measures for rural and remote communities have been available since 2011, enabling the delivery of health services via a telehealth model for eligible patients within these communities. While there are no allergy-specific telehealth services, private consultations are eligible for Medicare rebates to patients residing in eligible areas.

Targeted incentives such as the Workforce Incentive Program complement services available through Medicare, and support team-based and multi-disciplinary models of care. This program subsidises nurses and allied health providers for their time in General Practices, including the provision of allergy and/or telehealth services as required.

In addition, the telehealth items introduced in response to the COVID-19 health emergency have transitioned to permanent arrangements, effective 1 January 2022, enabling services to be delivered by GPs, specialists and allied health professionals via phone or video. This means telehealth is now more widely available across Australia.

As with telehealth services available since 2011, new telehealth medical and allied health consultations may be appropriate to claim for allergy-related advice, although the suitability of these services is a clinical judgement of the treating practitioner.

Recommendations 7 and 8

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

8: 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.*

Partially supported

The Government relies on a positive recommendation from the independent Medical Services Advisory Committee (MSAC) in order for a new medical service to be funded through the MBS (such as an item for a qualified practitioner to conduct a food or drug challenge). MSAC appraises new medical services and provides advice to Government on whether they should be publicly funded based on an assessment of its comparative safety, clinical effectiveness and cost-effectiveness, using the best available evidence. As such, an application to MSAC is required before a Government decision to MBS list a new service could be made. Anyone is able to submit an application to the MSAC, however due to the level of evidence required, a medical professional group is generally best placed to provide the necessary research and trial data. More information about the MSAC process is available at www.msac.gov.au.

The new Government funding for allergies will allow the National Allergy Council to examine and provide advice on the breadth, clinical effectiveness and cost effectiveness of allergy treatments and gather evidence required for a MSAC application.

The Government is supportive of public hospitals operating clinics for drug allergy de-labelling, and notes that some public hospitals have existing services. Where states and territories deliver de-labelling services as part of their public hospital immunology and allergy clinics and other specialist services, the Commonwealth makes a funding contribution towards the costs of these services through the National Health Reform Agreement arrangements. The MBS also contains several items which provide Medicare rebates for skin testing for allergens, including item 12004 for the testing of skin for drug allergens.

The new funding for the National Allergy Council will support it to engage with the Australian Commission of Safety and Quality in Health Care for the development of nationally standardised drug allergy de-labelling guidelines, with assistance from the new National Allergy Centre of Excellence.

Recommendation 9

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.*

Partially supported

Chlorhexidine and iodine must already be clearly identified on medicine labels as they are active pharmaceutical ingredients. Similarly, when present in medical devices, chlorhexidine and iodine are identified on labelling or packaging.

In addition, certain substances that are allergens or present health risks to some consumers must by law be declared on medicine labels. While not included on this list, latex has been identified for inclusion in the next update. Existing labelling requirements for medical devices also require the declaration of latex.

There are a number of alternatives to chlorhexidine and iodine registered for use by the Therapeutic Goods Administration (TGA), and the majority of medicines in vials do not use latex-containing vial stoppers. Decisions on procurement and establishment of product databases are a matter for the states and territory governments as they manage procurement for their hospital systems.

TGA publishes advice on risks of anaphylaxis from particular medicinal substances on its website and in the Medicines Safety Update, a publication that goes out on a regular basis

to healthcare professionals. For example, there was a recent warning in the Medicines Safety Update about the risk of anaphylaxis from chlorhexidine impregnated central venous catheters.

Recommendation 10

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.

Noted

The Royal Hobart Hospital is the sole manufacturer of Jack Jumper Ant (JJA) Active Pharmaceutical Ingredient (API) for venom immunotherapy treatment. However, API is not the final manufactured product given to patients undergoing immunotherapy treatment. The final manufactured product uses API to produce a clinical grade venom and diluent that can be supplied across state borders.

Presently, the Royal Hobart Hospital is the only hospital in Australia licenced by the Therapeutics Goods Administration (TGA) to manufacture JJA API, permitting distribution of API to other states and territories within Australia.

JJA API is supplied to Victoria and South Australia, which now have venom immunotherapy clinics available at Monash Health and the Royal Adelaide Hospital. The provision of venom immunotherapy treatment varies between states in cost, wait times, and delivery in private and public health systems.

The Australian Government notes funding to enable the Tasmanian JJA Program to continue expanding to other states and territories including Victoria, Southern New South Wales, Australian Capital Territory and South Australia. The Minister for Health and Aged Care will write to respective state and territory health ministers requesting consideration and further information on the cost of supporting this recommendation. The Australian Government will consider options based on this information, with key consideration to the significant labour involved in harvesting raw material from JJA, the extensive quality control testing before it can be distributed interstate and the Tasmanian JJA Program's capacity to increase supply.

Recommendation 11

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.

Supported in principle

The Government supports the automatic referral of allergy and anaphylaxis to the coroner, as this will build the evidence base to help inform health policy, interventions and research priorities. The Minister for Health and Aged Care will write to states and territories urging them to implement this recommendation.

Recommendation 12

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.*

Partially supported

Approval of a new medicine and its registration on the Australian Register of Therapeutic Goods may not result in multiple alternative adrenaline injections immediately becoming available for patients. While submission of an application of regulatory approval and on-going supply to the market is a commercial decision for suppliers, the TGA has met with sponsors of alternative adrenaline autoinjectors to encourage them to make a regulatory submission. In many instances, supply decisions are heavily dependent on PBS listing.

The TGA evaluates stability data provided by the company to confirm the maximum period during which the quality of a medicine can be reliably maintained. However, the active ingredient in Epipens, adrenaline, is chemically unstable, limiting the product's shelf-life.

The TGA has investigated the reasons for the intermittent shortages of adrenaline auto-injectors in recent years. There appear to be recurrent manufacturing problems which have impacted on supply across several countries. TGA has an active role in assisting with mitigation strategies when anticipated shortages are notified to the TGA (which is now mandatory following 2018 amendments to the Therapeutic Goods Act 1989).

In March 2021, the TGA approved the registration of three new adrenaline pen products (Anapen). The evaluation of these submissions was appropriately prioritised considering the

unstable supply of adrenaline containing medicines and their importance to Australians with allergy and anaphylaxis.

Recommendation 13

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).*

Supported in principle

The mix and volume of services delivered by public hospitals and the associated workforce composition is determined by state and territory governments and their public hospital administrators. Under the existing National Health Reform Agreement arrangements, the Commonwealth will provide a funding contribution towards the costs, including for workforce, of allergy and immunology services delivered by states and territories through their public hospitals.

The Government can provide data on the current allergist and immunologist workforce in hospitals but does not have any demand data to be able to review the sufficiency of the workforce. Under the National Medical Workforce Strategy, a data strategy is underway which includes supply and demand modelling work. The Minister for Health and Aged Care will write to his state and territory counterparts to request data which will assist with this work. Having an agreed demand methodology and improved data sets through the data strategy will support evidence-based policy and funding decisions on workforce in the future.

Training for allergists and immunologists is provided through advanced training positions in public hospitals and as such does not fit the criteria for the Commonwealth funded specialist training program. However, given the small specialist nature of this workforce, a collaborative approach between commonwealth and state and territory governments and the specialist college to conduct workforce planning for this cohort would be appropriate.

Recommendation 14

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.

Supported in principle

The Australian Industry and Skills Committee (AISC) is responsible for approving nationally recognised vocational education and training (VET) training packages for implementation and providing industry advice to Commonwealth, state and territory governments.

The AISC is supported in this role by a network of 67 Industry Reference Committees (IRCs), made up of industry experts who understand the skills needs of their sector, industry or occupation. VET Training Package qualifications are reviewed and updated regularly to reflect changes in technology, work practices or other regulatory changes. Processes are also in place to enable rapid training responses to urgent and emerging industry skills needs where required.

The Tourism, Travel and Hospitality IRC has reviewed the Cookery components of the SIT Tourism, Travel and Hospitality Training Package. Content regarding allergies and anaphylaxis and cross-contamination between foodstuffs and other items was updated during the course of this review. Updated qualifications were published to the national register on 10 June 2022, and are now available for delivery by Registered Training Organisations.

The new National Allergy Council will be funded to engage with Skills IQ and the Australian Skills Quality Authority to review existing accredited hospitality training courses and incorporate minimum standards for food allergen management training into these courses.

Recommendation 15

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.

Fully supported

The Allergen Bureau is an industry body which aims to share information and experience within the food industry on the management of food allergens. It administers the Voluntary Incidental Trace Allergen Labelling (VITAL) program. The VITAL program is a standardised risk assessment process for food industry to assess the potential impact of allergen cross-contact and to inform decisions regarding appropriate allergen management and labelling.

Since 2015, the Allergen Bureau has reported an increasing uptake of the VITAL Program both locally and internationally.

In 2019, the Allergen Bureau developed the VITAL Standard, which is a certification version of the VITAL program that provides for the use of a VITAL 'V' tick on packaging to inform consumers that a product has been through the process.

FSANZ recognises the critical importance of allergen labelling on food to help consumers living with food allergies make safe choices. FSANZ convenes the Allergen Collaboration, which includes representation from food manufacturing, food service, allergy support groups (including the Allergen Bureau), health professionals and government. The Collaboration works together to explore non-regulatory measures that can improve the management of food allergens.

FSANZ will work with the Allergen Bureau and the Collaboration to provide information on the VITAL program and encourage industry to use VITAL as a tool in its allergen management and labelling.

Recommendation 16

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.

Supported in principle

The previous Government provided funding to implement activities under the National Allergy Strategy, a partnership between ASCIA and A&AA. One of the activities is a nationally standardised training course for hospital food service to improve food provision in all hospitals. The free online course, *All about Allergens for Hospitals*, was launched in September 2020. It is aimed at all staff involved in the food service chain in a hospital and contains four different versions to ensure the training is applicable to the role of the staff member undertaking the training. The four versions are targeted at: kitchen managers and supervisors; kitchen staff; ward managers and nurses; and ward support staff. The training is available free of charge via the Food Allergy Training website: www.foodallergytraining.org.au.

The former Minister for Health wrote to the Chief Executive Officers of all hospitals in Australia in November 2020 to encourage them to make use of this resource. The Minister for Health and Aged Care will write to his state and territory counterparts urging them to mandate allergen regulations for all hospitals, including mandating training for hospital staff.

Recommendation 17

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.

Partially supported

Plain English allergen labelling (PEAL) was a proposal to amend the Australia New Zealand Food Standard Code (the Code) to introduce requirements to make allergen labelling clearer, more consistent and in plain English.

The Government supports this work to better enable food allergic consumers make safe food choices. Given the significance of the proposed changes, the Food Ministers Meeting (including the previous Australian Government ministers) supported a timeframe which allowed FSANZ to thoroughly complete its assessment processes, including consideration of the available evidence and public consultation.

In December 2020, FSANZ publicly notified that the FSANZ Board had approved the changes to the Code and notified the then Australia and New Zealand Ministerial Forum on Food Regulation (the Forum). As the Forum did not request a review of FSANZ's decision, the required changes to allergen labelling were gazetted and became law on 25 February 2021. The food industry has three years to transition to the new labelling requirements.

Recommendation 18

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.

Partially supported

In 2019, FSANZ consulted with key stakeholders on allergen risk management associated with food product reformulation including labelling.

The food industry reported on the various voluntary labelling practices that are used to alert consumers to the presence of a food allergen introduced as a result of reformulation. This includes changes to the statement of ingredients, front of pack statements (for example 'reformulated', 'new recipe' or 'check allergen advice'), or labelling devices such as flags or banners. Off-label practices, such as social media alerts, company website information and on-shelf product segregation between original and reformulated products, are also widely used. Some companies also notify allergy support groups, which then disseminate the information through their own networks.

Allergy support groups noted food allergic individuals are advised to always refer to the statement of ingredients, irrespective of being familiar with a food product to ensure the product can be safely consumed.

In 2019 the Australian Food and Grocery Council updated its best practice industry guidance[1] with advice to clearly differentiate products when recipe changes result in a change of allergen status.

The Government recognises the importance for food allergic consumers to be able to make safe food choice and supports the initiatives used by the food industry to alert consumers to reformulation where the allergen status of the food product has changed. FSANZ will work with the food industry and the Allergen Collaboration to promote these existing initiatives.

Recommendation 19

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

Supported in principle

The Government notes that ASCIA has already developed modular online education and training for staff at Australian primary and secondary schools for recognising and responding to anaphylaxis. The new National Allergy Council funding will allow ASCIA to continue to provide these educational resources and training for free for all users. The Minister for Education will write to the state and territory education ministers and non-government education authorities to advocate for all school staff to receive the specific training developed by ASCIA. The use of ASCIA's training will ensure high quality, nationally consistent, education and training materials are available across Australia.

The National Allergy Strategy used previous Government funding to develop *Best Practice Guidelines for the prevention and management of anaphylaxis in schools and children's education and care (ECEC)*, which were published in October 2021. The Best Practice Guidelines are available online on the Allergy Aware resource hub for schools and children's education and care services (www.allergyaware.org.au). The new 2022-23 funding for the National Allergy Council includes funding for a communication strategy, consumer education, and ASCIA e-training for schools, ECEC and the community. It will also allow for the Best Practice Guidelines to be progressed to minimum standards.

[1] AFGC and Allergen Bureau *Food Industry Guide to Allergen Management and Labelling for Australia and New Zealand* (2019)

Recommendation 20

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.

Supported in principle

The First Aid Industry Reference Committee is responsible for the national training package units of competency relating to first aid which underpin nationally recognised training in this area.

The *HLTAID011 Provide First Aid* unit of competency was updated in October 2020 and addresses the management of allergic reactions and anaphylaxis. This unit is included in over 300 nationally recognised training qualifications and is also widely delivered by Registered Training Organisations as a stand-alone first aid course.

Recommendation 21

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.

Supported in principle

The Government is committed to improving the effectiveness and capability of the teaching profession. The new funding for the National Allergy Council will allow it to scope the minimum requirements for including allergy in the curriculum for medical and education undergraduate degrees.

The *Accreditation of Initial Teacher Education Programs in Australia: Standards and Procedures* (the accreditation standards) require initial teacher education programs to prepare pre-service teachers to meet the Graduate career stage of the *Australian Professional Standards for Teachers* (the Teacher Standards). The Teacher Standards include a requirement under Focus Area 4.4 that teachers must maintain student safety and be aware of strategies that support students' wellbeing and safety within the school and/or system, curriculum and legislative requirements. However, the standards do not specify program content. As universities are autonomous entities established under state and territory legislation, decisions about course offerings and course content are a matter for universities.

The Department of Education will work through the Australian Council of Deans of Education to raise the visibility of this recommendation with Initial Teacher Education providers and encourage the inclusion of information about allergies and anaphylaxis in their course content.

Under the Education and Care Services National Regulations, early childhood education and care services must meet mandatory requirements in relation to staff members with first aid qualifications, anaphylaxis management training, and emergency asthma management training.

Vocational education and training qualifications relevant to learning support assistants, childcare workers, and workers in out-of-school-hours care settings were updated in May 2021.

The unit of competency *HLTAID012 Provide First Aid in and education and care setting*, which includes content relating to allergies and anaphylaxis, is included as a learning requirement (core unit) of the Certificate III in Early Childhood Education and Care, which is the entry level qualification for early childhood educators.

This unit is also included as a core unit in the relevant qualification for outside school hours care workers. The unit is an elective in the qualifications that support the learning support assistant job role.

Recommendation 22

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.*

Partially supported

The Government notes that major airlines have access to ASCIA resources such as anaphylaxis training, general use adrenaline autoinjectors, airline specific ASCIA Action Plans for Anaphylaxis that can be used as a poster and stored with first aid adrenaline autoinjectors, and other resources.

The Board of Airline Representatives of Australia (BARA), which represents 33 international airlines operating into Australia and carries 90 percent of international passengers to and from Australia, has advised that international airlines undertake a range of inflight practices

and carry a range of equipment to assist with customers requiring anaphylaxis care consistent with training and equipment requirements.

Where passengers notify airlines of their emergency care plans, action can be taken by the airline in responding to requests to wipe down seats, noting some passengers prefer to do this themselves at the time of boarding.

Qantas, Virgin Australia and BARA have advised that cabin crew are trained for a range of medical incidents. This includes recognising and managing anaphylaxis and awareness on the use of adrenaline auto-injectors, noting some passengers carry these with them in the cabin and wish to administer injections to themselves or have this done by a carer travelling with them.

International aircraft operators have also advised that they have medical kits which have supplies of Epi-Pens for adults and children.

Recommendation 23

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.

Fully supported

Through the Workforce Incentive Program (WIP), the Government is improving access to quality medical, allied health and nursing services in regional, rural and remote areas and supporting team-based care. The WIP – Practice Stream provides financial incentives of more than $400 million per year to encourage general practices across Australia to engage allied health professionals, nurses and Aboriginal and Torres Strait Islander Health Workers/Health Practitioners as part of a multidisciplinary team. Practices consider the needs of their community when determining which health professional (or combination of) to engage, which provides flexibility to address gaps in availability or accessibility of particular health services.

The Australian Government Department of Health and Aged Care is leading the development of Australia's first National Nursing Workforce Strategy (Strategy). The Strategy will set out a vision for the future of nursing in Australia as well as priorities to help support a capable, resilient nursing profession delivering person-centred, evidence-based, compassionate care across all sectors. The development of the Strategy will provide an opportunity for in-depth consideration of issues, from a range of perspectives, to influence the nursing workforce of the future.

A Nurse Practitioner 10 Year Plan (Plan) is also under development. The Plan will describe a set of actions that can be taken to address nurse practitioner workforce issues of national significance and enhance the delivery of nursing care to the Australian community. It will

have 1-3 year, 5 year and 10 year goals. Development of the Plan will occur concurrently with development of the National Nursing Workforce Strategy, due to the critical role nurse practitioners play in broader nursing career pathways and health care outcomes. The Strategy and the Plan will provide an opportunity for the Government to consider how the nursing workforce can support and work with allergy sufferers.

Recommendation 24

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.

Partially supported

The ACCC does not specifically regulate therapeutic goods, with regulatory responsibility for the safety and efficacy of these goods falling to the TGA. The ACCC seeks to avoid duplicating the supervisory activities of specialist regulators and cannot replicate the therapeutic based expertise that a specialist regulator like the TGA can deliver.

Reviews of medicines and devices are undertaken by the TGA on a risk-assessed basis and may be instigated in response to a variety of signals, such as an increased trend in adverse event reports, newly identified risks, reports of lack of efficacy, or reports from other international regulators, health care professionals or members of the public.

The TGA undertakes evidence reviews for particular products and product groups in response to these signals and has the powers to take a range of regulatory actions, including withdrawal of the market approval for the product, if the sponsoring company for the product does not hold evidence to support claims such as reliable diagnosis or treatment of allergies. However, funding and staffing resources would not permit a full review of all therapeutic goods (including medical devices) which claim to diagnose or treat allergies. In addition, the TGA does not have regulatory responsibility for the delivery of medical services.

Some products which claim to diagnose or treat allergies may be medicines and medical devices that are not included in the Australian Register of Therapeutic Goods (ARTG) (described as ‘unapproved’). These have not been evaluated by the TGA for quality, safety, efficacy or performance. For various reasons, there are times when approved and available products may not meet the needs of all patients and clinical situations. In recognition of this, there are provisions that allow doctors and patients to access ‘unapproved’ treatments from overseas. These provisions include the Personal Importation Scheme, Special Access Scheme (SAS) and Authorised Prescriber Scheme. The primary responsibility for the decision to use an ‘unapproved’ therapeutic good for a patient is placed on the prescribing medical

practitioner and they must obtain the informed consent of each patient for whom they prescribe an unapproved good.