Allergy & Anaphylaxis Australia

Committee Secretariat
Standing Committee on Health, Aged Care and Sport
PO Box 6021
Parliament House
Canberra ACT 2600

3 November 2020

Dear Standing Committee,

Allergy & Anaphylaxis Australia (A&AA) welcomes the opportunity to comment on the terms of reference of the House of Representatives parliamentary inquiry into approval processes for new drugs and novel medical technologies in Australia.

We thank the Australian government for considering the needs of Australians living with allergic disease in the context of the need for improved approval processes for new drugs and novel medical technologies.

A&AA is available to assist the Standing Committee as required throughout the Inquiry.

Yours sincerely,

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Background

Allergy & Anaphylaxis Australia (A&AA) is a registered charity, established in 1993 to support and assist those affected by allergy and anaphylaxis. A&AA is dedicated to assisting individuals, their caregivers and all in the community in the management of allergic conditions including food allergy. A&AA's aim is to enable individuals and their families to enjoy an optimal quality of life whilst minimising risk to their health and wellbeing.

A&AA strives to raise awareness of allergy in the community and provides evidence-based information, resources and services to support children and adults living with allergic disease including food allergy. A&AA has members across all states and territories of Australia. We have a Medical Advisory Board that consists of several clinical immunology/allergy specialists who are also members of Australia's peak medical body, ASCIA (the Australasian Society of Clinical Immunology and Allergy).

In 2014, a collaboration between A&AA and ASCIA, alongside many key stakeholder organisations, formed the foundations of the National Allergy Strategy (NAS) which was launched in 2015. The NAS continues to progress several initiatives including food allergy prevention, a youth project, free education for staff working in food service, a clinical care standard for anaphylaxis, a shared care model for allergic disease, an anaphylaxis register, minimum standards for school and childcare, a drug allergy project and more. See www.nationalallergystrategy.org.au

1.The range of new drugs and emerging novel medical technologies in development in Australia and globally, including areas of innovation where there is an interface between drugs and novel therapies

Improved understanding of allergic disease will positively impact the health and wellbeing of individuals and families managing allergic disease, including IgE and non IgE mediated food allergy, those at risk of anaphylaxis due to all causes, atopic dermatitis, allergic rhinitis and allergic asthma.

Currently, A&AA encourages individuals at risk of anaphylaxis to always carry two adrenaline autoinjectors as approximately 10%-20% of those that experience anaphylaxis require a second dose of adrenaline. EpiPen® is currently the only brand of adrenaline autoinjector available in Australia and the device is approximately 15.5cm long and 10cm in circumference in its protective case. EpiPen®s need to be kept between 15 and 25 degrees Celsius. This is problematic in the Australian climate. Other countries have access to autoinjector devices that are smaller and talk the user through the administration process (Auvi Q®) and come in doses suitable for infants (Auvi Q®) and teens/adults over 60kg (Anapen®, Emerade®). Australians should have the ability to choose an option that most suits their needs.

Whilst some researchers have begun the process of looking into novel ways to carry and then administer adrenaline in Australia and globally, the cost of research and development becomes prohibitive. A device that is incorporated into a smart phone or smart watch would increase the likelihood of people having adrenaline available to them at all times. Other research includes adrenaline administration via a nasal spray, inhaler or sublingual wafer or tablet. These (non-injector) methods of adrenaline administration would help to increase the proportion of those at-risk of anaphylaxis who carry adrenaline. They would also likely improve the rate of timely adrenaline administration, thus reducing the risk of fatal anaphylaxis.

An adrenaline administration device/medication that is more temperature stable and available in a variety of doses based on weight, including a dose for infants and a dose for teens/adults over 60kg, which Australia currently does not have access to would make a difference in the lives of Australians at risk of anaphylaxis.

A&AA would like Australia to contribute to the development of novel technologies to administer adrenaline during anaphylaxis. We also need innovative ways of assessing if someone is experiencing anaphylaxis as often there is doubt (even for health professionals) and adrenaline administration is often delayed. As potentially life threating allergic disease is a growing phenomenon, A&AA asks the Australian government to support novel ways of decreasing risk and treating anaphylaxis into the future.

Recommendations:

- increasing investment in allergy/immunology research to assist the growing number of Australians living with allergic disease with diagnosis, management, emergency treatment and possible cures.

- increasing investment in research into novel ways of delivering adrenaline during anaphylaxis. This may include via sublingual wafer or tablet, inhaler, nasal spray or an injector device incorporated into a smart phone or watch.

- that novel methods (such as a smart watch or smart phone app) are investigated to help the consumer/patient diagnose anaphylaxis events

- that Australia has access to adrenaline autoinjectors that are currently available overseas which offer doses for infants (E.g. Auvi Q®) and teens/adults over 60kg (E.g. Anapen®, Emerade®) and smaller device size that talks the user through the administration process and is easily carried by the individual at-risk of anaphylaxis (E.g. Auvi Q®). An option that is more temperature stable for the Australian climate will decrease anxiety and give confidence the medication will reverse an anaphylaxis when administered.

2.Incentives to research, develop and commercialise new drugs and novel medical technologies for conditions where there is an unmet need, in particular orphan, personalised drugs and off-patent that could be repurposed and used to treat new conditions;

The use of Pharmaceutical Benefits Scheme (PBS) listed drugs that may have been registered/ designed for management of one allergic condition, but are used to treat another allergic condition, is not uncommon in allergic disease. For example, in eosinophilic oesophagitis (EoE) a corticosteroid such as Flucitasone (Flixotide®) is swallowed and not inhaled as it is when used to treat asthma; in chronic rhinosinusitis, steroids, such as Budesonide (Pulmicort®), which are usually inhaled for asthma are used in sinus irrigation. Neither of these uses have PBS subsidy, but are commonly accepted long and short-term treatments for these conditions.

The current model of PBS listing means that there is little incentive for the pharmaceutical companies to apply for the use of their drugs for other conditions. Importantly, the person with allergic disease often has several allergic conditions. A medication that is PBS listed for one allergic condition that is used to treat another allergic condition successfully should be considered by the Australian Government so people whose quality of life is impaired can be improved. Equity in healthcare is a critical concern. The cost of medications to treat allergic disease is out of reach for

some, and suboptimal management predisposes them to the development of more severe allergic disease that has a greater impact on their quality of life and the healthcare system.

There are currently available biologic drugs which modulate the immune response. These drugs may be useful for treating a range of allergic conditions, however research funding is required to investigate the potential uses of these drugs.

Recommendations:

- provision of avenues for PBS listed drugs that are proven to work for one allergic condition to be PBS listed for other allergic conditions where other medications are not as effective in controlling symptoms to improve quality of life.
- provision of avenues for drugs that are proven to be effective for allergic conditions internationally to be fast-tracked for registration and PBS listing in Australia.
- fund research into biologic immune modulating drugs to treat a range of allergic conditions.

3.Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies;

A&AA would like to see Australia become a world leader in clinical trials for new allergy treatments and drugs. While there has been an increase in allergy research in Australia since the 1990's there are many potential research projects on hold because of inadequate available funds and resources. Australia has been labelled as 'the food allergy capital of the world.' It would be advantageous for Australian researchers, government and consumers to engage in more international clinical trials of new treatments and medical technologies. Increased government funding would allow more research and hopefully decrease the time to medication registration, especially where existing treatments have adverse effects, are not effectively improving a condition or are suboptimal for another reason. To our knowledge a very small percentage of Australia's research funds are allocated to allergic disease and its management.

There is even less research into allergic disease states that are not common. These include but are not limited to EoE, Food Protein Induced Enterocolitis Syndrome (FPIES), mastocytosis, chronic spontaneous urticaria and mammalian meat allergy after tick bite. The fact that the prevalence of these allergic conditions is smaller than other allergic conditions, such as eczema or allergic rhinitis, should not mean there is no or very little research into these conditions because they greatly impact quality of life.

Having more research in Australia could improve access to needed medications and treatments in a timely manner. A drug that has been approved for a clinical trial in Australia could possibly progress through the registration and PBS listing process via a less lengthy pathway depending on outcomes of the clinical trials.

A national registry of consumers with various allergic conditions would make research in Australia much more attractive. A registry would assist researchers with finding suitable clinical trial candidates for the various allergic conditions.

Increased use of telehealth consultations within the clinical trial setting when possible, would help to facilitate more cost-effective trials and potentially have an increased number of people making themselves available for research because there is less lost time in travelling to and from appointments at research centres.

For allergic conditions with a lower prevalence, such as EoE, it is difficult to find enough patients to enrol in randomised control trials, so Australia needs to collaborate with international trials which are statistically powered to show meaningful results.

Recommendations:

- Increased funding for clinical trials of food allergy treatments
- Funding for a national registry of patients with allergic disease to assist in finding suitable clinical trial participants.
- Increased funding to help in the treatment of less common allergic conditions which greatly impact quality of life.
- Increased use of telehealth technologies in research trials to increase participation and decrease trial costs.
- That Australia collaborate with other countries internationally to participate in trials of less common allergic conditions so that the trial can have increased statistical power and gain meaningful results earlier.

4.Without compromising the assessment of safety, quality, efficacy or cost-effectiveness, whether the approval process for new drugs and novel medical technologies, could be made more efficient, including through greater use of international approval processes, greater alignment of registration and reimbursement processes or post market assessment.

Australians should have access to regulated pharmaceuticals for healthcare, as those available internationally. In Australia, we lack access to a significant number of medicines available overseas due to the onerous regulatory processes. Further, drugs can take longer to become available in Australia compared to other countries. For example, Dupilumab has been used globally as a treatment for severe atopic eczema for a number of years.

Although Australia has alliances with other countries for more rapid approval, Dupilumab has undergone three years of applications, public submissions and government discussions. Although the life changing product was recommended for PBS listing by the Pharmaceutical Benefits Advisory Committee (PBAC) over seven months ago, people are desperately waiting for the medication to be PBS listed. People's lives are on hold because of the severity of their atopic eczema while the sponsor and the government negotiate a way forward. The fact that Dupilumab is back on the agenda for the November 2020 PBAC meeting is gut wrenching for many, including those that decided to pay the $1600/month because they simply could not wait any longer.

A&AA pleads with the government for a more efficient registration and PBS listing process without jeopardising consumer safety. We ask that there is improved utilisation of the Comparable Overseas Regulator Pathway for medicines and work-sharing with the Australia-Canada-Singapore-Switzerland (ACSS) Consortium.

Recommendation:

- That Australia adopt a more efficient approval process for medication already accessible in countries Australia has trusted relationships with, without compromising safety, quality, efficacy and cost.