Allergy & Anaphylaxis Australia

Professor Andrew Wilson

Chair Pharmaceutical Benefits Advisory Committee (PBAC)
MDP 952, GPO Box 9848
Canberra ACT 2601

8th September 2020

Dear Professor Wilson,

**Re: Anapen® adrenaline (epinephrine) autoinjector application**

Allergy & Anaphylaxis Australia (A&AA) has been notified by Allergy Concepts of their application to the Therapeutic Goods Administration (TGA) for registration and the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the Pharmaceutical Benefits Scheme (PBS) of the Anapen® adrenaline autoinjector. We are now aware the application will be discussed at the November 2020 PBAC meeting.

A&AA strongly supports the application of Anapen® to be listed on the PBS for the following reasons:

- Anapen® has a 500mcg dose making it a more suitable dose for people 50kg and over than the current option of the EpiPen® which is 300mcg. The 500mcg dose may reduce the need for a second dose of adrenaline in an anaphylaxis event in people over 50kg.

- An alternative autoinjector will offer options for the Australian population who are at-risk of anaphylaxis

- Recalls of the only currently available adrenaline autoinjector EpiPen® have meant that some people have been left with no (or only one) adrenaline autoinjector. An alternative registered device will improve safety by ensuring those at risk of anaphylaxis have options.

- EpiPen® shortages have meant people have had no choice but to carry and use expired adrenaline in life-threatening emergencies.

- An alternative autoinjector registered on the PBS will help to ease the pressure on both devices if there is an issue (i.e. a recall, shortage, contamination) with one or the other.

**Background**

EpiPen®, the only adrenaline autoinjector currently available in Australia, has been available since the early 1990's. The spike in EpiPen® shortages since the 2017 EpiPen® recalls have confirmed the need for other adrenaline autoinjectors to be registered and PBS listed in Australia.

EpiPen® shortages have a great impact on individuals at risk of anaphylaxis and their families. The shortages increase the burden of management of severe allergy and risk of anaphylaxis. Having multiple devices available and having

the ability to choose which device is best suited to an individual is what A&AA aspires to as the advocate for those living with the risk of anaphylaxis.

Safety is compromised when we have EpiPen® shortages. People mitigate risk in different ways and A&AA has been alarmed at the actions of some managing the risk of anaphylaxis, including health professionals. A&AA has spoken with parents of at-risk children, individuals at risk and childcare staff caring for children at-risk who have not administered an EpiPen® when indicated because of fear they would not be able to replace it or because the device in-hand had expired. We have also had ill-informed GPs and pharmacists show people how to draw up adrenaline using an ampoule, needle and syringe. This is not best practice for lay people managing life-threatening emergencies in the community setting.

In more recent years, Anapen® has launched the 500mcg dose device. This is a point of difference A&AA welcomes. Currently, someone weighing 20kg or 100kg is prescribed the 300mcg dose of EpiPen®. A 300mcg dose may not be sufficient to reverse the signs and symptoms of anaphylaxis in a 100kg individual. We rely on these people having a second device available or an ambulance arriving promptly so further doses can be administered. It is anticipated that Anapen® 500mcg will be offered to people weighing 50kg and over. A 500mcg dose of adrenaline would give them a dose of adrenaline that is in line with appropriate dosing schedules for their weight. A&AA supports having the 500mcg dose available for those over 50kg as per recommendations from Australasian Society of Clinical Immunology and Allergy (ASCIA).

A&AA, as the trusted charity for allergy support, provides education and resources to not only individuals and their families living with allergy, but also the wider community. As CEO and a registered nurse, I have been communicating with Allergy Concepts regarding the planned launch of another device into the Australian market. Allergy Concepts are working with A&AA and A&AA has been assured of funding support to assist in creating new resources to help educate the community and health professionals about Anapen® and to update existing relevant resources should the Anapen® application be approved.

Thank you for considering the information put forward in this submission. Please do not hesitate to contact me for further information.

Yours sincerely,

Maria Said AM
Chief Executive Officer
**Allergy & Anaphylaxis Australia**