

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

9th September 2020

Dear Professor Wilson,

Re: SYMJEPI® adrenaline (epinephrine) injector application

Allergy & Anaphylaxis Australia (A&AA) noted SYMJEPI[®] registration and Pharmaceutical Benefits Scheme (PBS) listing was considered at the July 2020 Pharmaceutical Benefits Advisory Committee (PBAC) meeting. Emerge Health has been in communication with A&AA and the Australasian Society of Clinical Immunology and Allergy (ASCIA) since early 2020.

A&AA strongly supports the registration and PBS listing of SYMJEPI® for the following reasons:

- SYMJEPI[®] is a smaller, lighter weight adrenaline injector device compared to EpiPen[®] the only adrenaline autoinjector device currently available in Australia. Although it has a visible needle and is an injector rather than an autoinjector, some people may prefer SYMJEPI[®] because of its size and/or weight.
- An alternative injector 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 lifethreatening emergencies.
- An alternative injector 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.

SYMJEPI[®] provides the advantage of being a pre-filled syringe that is compact in size and light in weight. These features would be particularly beneficial for adolescents and adults at risk of anaphylaxis who must carry adrenaline injectors and prefer to carry their devices in their pocket or a small bag. We feel this ease of carriage may encourage better adherence to recommendations to always carry their adrenaline injector on their person.

A&AA is aware of mechanical complaints where devices have failed to inject adrenaline in an emergency. Several brands of adrenaline autoinjectors have been recalled because of this problem in Australia and globally. The absence of the automatic mechanism may mean it is less likely for SYMJEPI® to fail in an emergency.

While some parents of children at risk of anaphylaxis and school/childcare facilities may be reluctant to use this device because it is an injector with an exposed needle and not an autoinjector, many health professionals and

healthcare facilities that currently have adrenaline autoinjectors for use in an emergency, may see SYMJEPI® as a suitable option.

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 autoinjector/injectors 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. A pre-filled syringe is a much better option as lay people do not need to break open an ampoule and draw up the amount of required adrenaline in a life-threatening emergency.

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. Emerge Health continues to work with A&AA and ASCIA. A&AA has been assured of funding support to assist in creating new resources to help educate the community and health professionals about SYMJEPI[®] and to update existing relevant resources should SYMJEPI[®] be registered in Australia.

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