

23 February 2021

Attention: Dr Monique Stone
Clinical Lead and Director, Advanced Therapies Unit
Prescription Medicines Authorisation Branch
Australian Government Department of Health
Therapeutic Goods Administration TGA
PO Box 100, Woden ACT 2606, Australia
Monique.Stone@health.gov.au
Copy: Catherine Chan streamlinedsubmission@health.gov.au

Dear Dr Stone,

Re: ASCIA response regarding Anapen adrenaline (epinephrine) autoinjector application

We write to you on behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) in response to your letter of 21 February 2021.

In September 2020 ASCIA sent a letter of support to the Pharmaceutical Benefits Advisory Committee (PBAC), after being informed by Allergy Concepts that they had submitted an application to TGA for Anapen adrenaline autoinjectors, for consideration by the Therapeutic Goods Administration (TGA) and PBAC, for TGA approval and listing on the Pharmaceutical Benefits Scheme (PBS).

The letter from ASCIA to the PBAC outlined the ways in which ASCIA could assist in supporting the safe and effective use of Anapen adrenaline autoinjectors, in addition to guidance on weight.

As stated in the letter to the PBAC, ASCIA welcomes the availability of Anapen as an alternative adrenaline autoinjector in Australia for the following reasons:

- Having just one brand of adrenaline autoinjector (EpiPen), has meant that in times of product shortages, there has been no alternative for Australians at risk of potentially life threatening severe allergic reactions (anaphylaxis). This has caused risks, as well as panic buying and stockpiling, which has disadvantaged many Australians.
- An advantage of Anapen is the availability of a 500mcg version, which meets a currently unmet clinical need, for a higher dose than the 300mcg device.

As most people who administer adrenaline autoinjectors are not health professionals, education and training is required, to avoid incorrect use that can result in fatalities or disabilities, due to inadvertently undertreating anaphylaxis.

Allergy Concepts are aware that ASCIA is the main provider of accessible, consistent and evidence-based online anaphylaxis resources, education and training for health professionals and the community, which are available open access at www.allergy.org.au/anaphylaxis

The ASCIA website contains world leading, open access and free of charge online resources, education and training, including ASCIA Guidelines, ASCIA Action Plans for Anaphylaxis and ASCIA anaphylaxis e-training courses that have specific modules on the use of adrenaline autoinjectors.

ASCIA has been developing anaphylaxis resources since 2003, so we have considerable expertise in this area.

Allergy Concepts are also aware that these resources and courses will require updating if the Anapen application is approved. They are prepared to provide an unrestricted educational grant to ASCIA, to support the costs of these updates.

Allergy Concepts has recently informed ASCIA about comments from the TGA regarding the Anapen Product Information (PI) leaflet.

In response these comments, ASCIA recommends that Allergy Concepts change the Anapen PI leaflet to be consistent with ASCIA Guidelines, as follows:

- **Anapen 150mcg minimum weight of 7.5 kg, for children 7.5* to 20 kg** (generally less than 5 years).
- **Anapen 300mcg minimum weight of 20 kg, for adults and children over 20 kg** (generally 5 years or older).
- **Anapen 500mcg minimum weight of 50 kg, for adults and children over 50 kg** (generally older than 16 years).

ASCIA prefers to use weight, rather than age as a guide, as weight at the same age can vary widely between different ethnic groups, but weight is included above in brackets, in case it is required.

As stated on the ASCIA website, the ASCIA dosage recommendations (listed above) are based on expert opinion regarding recommended dose for weight and clinical trials of injected adrenaline in children, which is currently at variance (with slightly higher dosage) than the dosage stated in the PI leaflets. Reference: www.allergy.org.au/hp/anaphylaxis/adrenaline-autoinjector-prescription:

Furthermore, if in doubt, it is better to use an adrenaline autoinjector, than not use it, even if in hindsight the reaction is not anaphylaxis. Under-treatment of anaphylaxis is more harmful (and potentially life threatening), than over-treatment of a mild to moderate allergic reaction. If in doubt, give the adrenaline autoinjector. Reference: www.allergy.org.au/hp/anaphylaxis/adrenaline-autoinjectors-faqs

From our perspective, it is preferable if the PI leaflet for Anapen (and any other adrenaline autoinjectors) is aligned to ASCIA guidelines, to prevent confusion for prescribers and patients.

Please do not hesitate to contact us by emailing jill@allergy.org.au or phoning 0425216402 if you require further information.

Yours sincerely,



Dr Katie Frith
Chair, ASCIA Anaphylaxis Committee



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