

5.15 ADRENALINE

I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector and I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector. Adrenaline Auto Inject Jr Sun-JV® 150 and Adrenaline Auto Inject Sun-JV® 300, Ranbaxy Australia (Sun Pharma)

1 Purpose of Application

- 1.1 The minor submission sought to list a new adrenaline auto injector (Adrenaline Auto Inject Sun-JV) under the same conditions as existing adrenaline auto injectors (EpiPen, EpiPen Junior and Anapen) but with a different administration technique.

2 Requested listing

- 2.1 The submission requested identical listing price, pack size and authority conditions as EpiPen. As for EpiPen and Anapen, a caution stating that the products have a different administration technique and should not be prescribed to the same patient without training in their use, is proposed to be added to the restriction for Adrenaline Auto Inject Sun-JV.

For more detail on PBAC's view, see section 6 "PBAC outcome".

3 Background

- 3.1 Adrenaline (Adrenaline Auto Inject Sun-JV) was submitted to the TGA on 14 December 2014 as a generic equivalent to EpiPen with a TGA decision letter expected in April 2016. As the product was submitted as a generic application to the TGA, there will be no clinical evaluation report or delegate's overview, and will not be reviewed by the ACPM.
- 3.2 The TGA registration dossier included information to demonstrate that the new product is therapeutically equivalent to EpiPen in terms of concentration and route of administration.

For more detail on PBAC's view, see section 6 "PBAC outcome".

4 Clinical place for the proposed therapy

- 4.1 As for existing adrenaline auto-injectors, Adrenaline Auto Inject Sun-JV is for use in severe allergic reactions due to insect stings or bites, foods, drugs or other allergens.
- 4.2 While the product is a generic equivalent of EpiPen, the technique for injection differs. The EpiPen injection technique requires that the device be struck against the mid-thigh with sufficient force to trigger the intramuscular injection. However, the Adrenaline Auto Inject Sun-JV device requires the device to be placed firmly against

the injection site with the tip completely depressed and then triggered by clicking on an activation button.

- 4.3 In addition, a user of the new device is able to confirm that the dose has been delivered as the inspection window changes colour.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from two professional organisations, which stated that correct administration technique is critical, and that any device with a new administration technique would require widespread education and training.

Clinical evidence

- 5.3 The submission to the TGA was asked to consider Adrenaline Auto Inject Sun-JV and EpiPen brands of adrenaline as generic equivalents of each other therefore, no clinical evidence has been provided to support PBS listing.

Economic analysis

- 5.4 The proposed price is the same as EpiPen: DPMQ \$96.43

Estimated PBS usage & financial implications

- 5.5 The minor submission estimated there to be no financial implications to the PBS of listing the new product as the submission expects Adrenaline Auto Inject Sun-JV to only substitute EpiPen, and both drugs have the same price.

For more detail on PBAC's view, see section 6 "PBAC outcome".

6 PBAC Outcome

- 6.1 The PBAC recommended listing a new adrenaline auto injector (Adrenaline Auto Inject Sun-JV) under the same conditions as existing adrenaline auto injectors (EpiPen, EpiPen Junior and Anapen) on the basis that it is bioequivalent to EpiPen.
- 6.2 The PBAC noted that various adrenaline auto injector products have different administration techniques and should not be prescribed or dispensed to a patient without adequate training in their use. The PBAC therefore considered that the various brands of adrenaline auto injector should not be considered equivalent for the purposes of substitution (i.e. 'a' flagged in the Schedule).

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- 6.3 The PBAC noted that this was submitted to the TGA as a generic regulatory application, and considered that the minor submission's claim of bioequivalence with EpiPen is reasonable.
- 6.4 The PBAC noted that this new listing would trigger a 16% statutory price reduction to the drug adrenaline with manner of administration injection.
- 6.5 The PBAC recommended Adrenaline Auto Inject Sun-JV should be treated as interchangeable on an individual patient basis with EpiPen and Anapen under section 101(3BA) of the National Health Act.
- 6.6 The PBAC recommended Adrenaline Auto Inject Sun-JV be included in the PBS medicines for prescribing by nurse practitioners.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review because the PBAC has made a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and
ADRENALINE Injection 150 microgram/0.3 mL Injection 300 microgram/0.3mL	1	0	Adrenaline Auto Inject Sun-JV	Ranbaxy Australia

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
PBS Indication:	Acute allergic reaction with anaphylaxis
Treatment phase:	Initial sole PBS-subsidised supply for anticipated emergency treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.
Prescriber Instructions	The name of the specialist consulted must be provided at the time of application for initial supply.
Administrative Advice	No applications for repeats will be authorised. The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au). Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen, EpiPen or Adrenaline Auto Inject Sun-JV) at any one time.
Cautions	EpiPen, Anapen and Adrenaline Auto Inject Sun-JV products have different administration techniques and should not be prescribed to the same patient without training in their use.

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Clinical criteria:	Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.
Administrative Advice	No applications for repeats will be authorised. The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au). Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen, EpiPen or Adrenaline Auto Inject Sun-JV) at any one time.
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Clinical criteria:	Patient must have previously been issued with an authority prescription for this drug.
Administrative Advice	No applications for repeats will be authorised. The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au). Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen, EpiPen or Adrenaline Auto Inject Sun-JV) at any one time.
Cautions	EpiPen, Anapen and Adrenaline Auto Inject Sun-JV products have different administration techniques and should not be prescribed to the same patient without training in their use.

- 7.2 Amend existing listing as follows:
Update administrative advice and caution for item codes 3408J, 3409K, 8697R, 8698T to include the brand name Adrenaline Auto Inject Sun-JV

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The sponsor had no comment.