

MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY THE SECRETARIAT FOR CONSIDERATION BY THE COMMITTEE

14.02 VARIOUS INSECT ALLERGEN EXTRACTS, Stallergenes Australia Pty Ltd

1 Purpose of Application

1.1 Due to a supply shortage of several insect allergen extracts, the submission requested temporary listings for the following substitute products as alternatives for the currently listed bee venom, paper wasp venom and yellow jacket venom products:

- Insect allergen extract – honey bee venom, injection set containing 550 micrograms with diluent, Hymenoptera Honey Bee Venom[®],
- Insect allergen extract - paper wasp venom, injection set containing 550 micrograms, Hymenoptera Paper Wasp Venom[®], and
- Insect allergen extract - yellow jacket venom, injection set containing 550 micrograms, Hymenoptera Yellow Jacket Venom[®].

2 Requested Listing

2.1 The submission requested identical listing pack size and authority conditions as the current honey bee, paper wasp and yellow jacket venom listings.

2.2 The sponsor has requested higher prices for all three venoms and will not list Hymenoptera Paper Wasp Venom and Hymenoptera Yellow Jacket Venom unless higher prices are agreed. The sponsor cited higher prices from the alternative supplier as the reason for the price increase request. The details of the request are as follows:

Name	PBS listing status	Current AEMP	Requested AEMP	Fiscal impact of price increase over 5 years	s19A(1) approval ends
INSECT ALLERGEN EXTRACT – HONEY BEE VENOM Injection set containing 550 micrograms with diluent Hymenoptera Honey Bee Venom®.	Listed 1 July 2018	\$199.55	\$256.38	\$1,591,460	29 May 2019
INSECT ALLERGEN EXTRACT – PAPER WASP VENOM Injection set containing 550 micrograms with diluent Hymenoptera Paper Wasp Venom®	Not yet listed	\$199.55	\$300.89	\$105,430	29 May 2019
INSECT ALLERGEN EXTRACT – YELLOW JACKET VENOM Injection set containing 550 micrograms with diluent Hymenoptera Yellow Jacket Venom®	Not yet listed	\$199.55	\$349.38	\$72,945	29 May 2019

3 Background

- 3.1 The sponsor has been unable to guarantee supply of the currently listed Albey Honey Bee Venom (PBS item 2886X), Paper Wasp Venom (2918N) and Yellow Jacket Venom (2883R). This is similar to a request in January 2016 for bee, paper wasp and yellow jacket venom and for bee venom in May 2017.
- 3.2 The Therapeutic Goods Administration (TGA) approved the importation and supply of the three insect allergen extract in Australia, under Section 19A(1) of the Therapeutic Goods Act 1989.

4 PBAC Outcome

- 4.1 The PBAC recommended the temporary listings of the three insect allergen extracts, including honey bee venom, paper wasp venom and yellow jacket venom on the PBS to address the current supply shortage.
- 4.2 The PBAC considered there is a clinical need to maintain supply of these insect allergen extracts on the PBS. The PBAC considered the listings should remain during the validity of the Section 19A(1) approvals by the TGA.
- 4.3 The PBAC considered that listings should be under the same conditions as the PBS-listed insect allergen extracts.
- 4.4 The PBAC considered that a price premium requested was appropriate, however advised that this should only exist for the duration of current Section 19A(1) approval, which lapses on 29 May 2019. Following the end of this current Section 19A(1) approval, any request to maintain the higher price would require a minor submission to the PBAC to justify the price requested.

Outcome: Recommended

5 Recommended listing

Add new item – same restriction for item 2886X, 2918N and 2883R

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
INSECT ALLERGEN EXTRACT – HONEY BEE VENOM Injection set containing 550 micrograms with diluent	1	0	Hymenoptera Honey Bee Venom®	Stallergenes Australia Pty Ltd

Category / Program	General Schedule
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing (Private) <input type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic (Private) <input type="checkbox"/> Streamlined (Public)

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
INSECT ALLERGEN EXTRACT – PAPER WASP VENOM Injection set containing 550 micrograms	1	0	Hymenoptera Paper Wasp Venom®	Stallergenes Australia Pty Ltd

Category / Program	General Schedule
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing (Private) <input type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic (Private) <input type="checkbox"/> Streamlined (Public)

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
INSECT ALLERGEN EXTRACT – YELLOW JACKET VENOM Injection set containing 550 micrograms	1	0	Hymenoptera Yellow Jacket Venom®	Stallergenes Australia Pty Ltd

Category / Program	General Schedule
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing (Private) <input type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic (Private) <input type="checkbox"/> Streamlined (Public)

6 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.

7 Sponsor's Comment

The sponsor had no comment.