



australasian society of clinical immunology and allergy

## Information regarding the status of allergen shortages in Australia and New Zealand

12<sup>th</sup> January 2016

### What is allergen immunotherapy?

- Allergen immunotherapy (commonly known as “desensitisation”) is used to treat allergic rhinitis (hay fever) and allergic asthma, and to reduce the risk of dangerous allergic reactions to bee or wasp stings (anaphylaxis).
- It involves regular administration of the substance to which the patient is allergic (the allergen extract) either by injection or by mouth (sublingually).
- Injection treatment usually begins with weekly injections for several months, then continues monthly for several years.

[www.allergy.org.au/patients/allergy-treatment/immunotherapy](http://www.allergy.org.au/patients/allergy-treatment/immunotherapy)

### Origin of allergen extracts

- Allergen extracts are purified preparations of allergenic substances including pollens, house dust mite allergens, pet (dog, cat) allergens and insect (bee, wasp) venoms.
- Allergen extracts are commercially produced by pharmaceutical companies.
- As there are no Australian or New Zealand producers of allergen extracts, we are dependent on importation from overseas.

### Recent problems with Stallergenes allergen extract supply

- The most commonly used allergen extracts in Australia are imported from the company Stallergenes in France and distributed by their local subsidiary.
- Stallergenes (France) has encountered problems with allergen manufacture, labelling and supply during 2015, caused by the institution of a new IT system.
- This has affected the supply of allergen extracts used for immunotherapy in Australia, New Zealand and Europe.
- Originally, Stallergenes advised that shortages were to be a short-term only, lasting 1-2 months, but they are now extending into 2016.
- Information provided by Stallergenes regarding allergen supply and re-supply has changed on a number of occasions in the last 6 months.
- French health authorities have temporarily closed the Stallergenes manufacturing and labeling plant in December 2015.
- At the time of writing (12<sup>th</sup> January 2016), the date of re-supply of Stallergenes allergens remains unclear and almost no allergen extracts, apart from Oralair (which is inappropriate for the majority of our patients), are available from Stallergenes in Australia or New Zealand.
- This has already forced many patients to stop their treatment and will impact increasing numbers of patients as the shortage continues.
- The safety of immunotherapy depends on regular allergen administration. If treatment is interrupted, the treatment course may need to be re-started from the beginning.
- While other brands of allergen extracts are available for importation and use, these extracts are not interchangeable with the Stallergenes products. Patients switching to a different brand

would need to re-start from the beginning.

- Stallergenes has informed ASCIA that importation of bee and wasp venom extracts from North America is due to commence late January 2016. These venom extracts are from the same manufacturer as those currently available, and hence will be interchangeable with current venom products.
- As venom extracts are imported via a different route, there is no information at the time of publication (12<sup>th</sup> January 2016) whether they will be subsidized by the Australian Government PBS (substitutes will be subsidized by the NZ Pharmac scheme). A PBS subsidised prescription costs AU\$38.30 per 6 months (or \$6.20 concessional), whereas a non-subsidised prescription would cost approximately \$280 per 6 months.
- Stallergenes and ASCIA are communicating with the PBS to request urgent listing for the substitute venom products. In the meantime, patients may be able to seek reimbursement from their private health funds if they have pharmaceutical cover.

### **Caveat**

- Issues surrounding supply of allergen extracts are outside the control of ASCIA or individual medical practitioners.
- Information provided at the time of writing is subject to change, and is derived from the primary source of information, Stallergenes Australia.

### **Primary source of allergen availability and supply**

As the allergen extract manufacturer in France and local distributor, Stallergenes is the primary source of up to date information on allergen extract supply and related issues.

Additional information on relevant issues (e.g. allergen supply or rebates for allergen extracts ordered but not supplied) may be obtained from Stallergenes Australia:

Telephone: (02) 9979 0700

If in Australia:

1 800 635 306 for patients

1 800 500 499 for healthcare professionals

Web address: <http://stallergenesgreer.com/about-us/announcement/>

**For further ASCIA updates, please visit the ASCIA website: [www.allergy.org.au](http://www.allergy.org.au)**