

20 March 2017

## Alphapharm Initiates Recall of EpiPen® Auto-Injector in Australia

### EpiPen® 300 microgram (µg) Adrenaline Injection Syringe Auto-Injector Batches 5FA665, 5FA6651, 5FA6652, 5FA6653

Alphapharm Pty Ltd, following consultation with the Therapeutic Goods Administration, is recalling the following batches of EpiPen® 300 microgram (µg) Adrenaline Injection Syringe Auto-Injectors due to the potential that these devices may contain a defective part that may result in the device failing to activate or requiring increased force to activate.

Batch number	Expiry
5FA665	Apr 17
5FA6651	Apr 17
5FA6652	Apr 17
5FA6653	Apr 17

Two reports world-wide have been confirmed of the device failing to activate in a batch of about 80,000 devices.

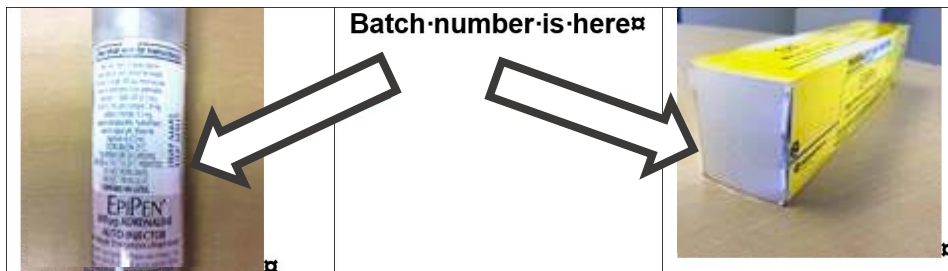
EpiPen® Auto-Injector is used for the treatment of allergic emergencies (anaphylaxis). The failure of the auto-injector to activate may result in patients not receiving the required dose of adrenaline resulting in the worsening of symptoms of anaphylaxis or anaphylactic reactions, which could be life threatening.

The recalled product was manufactured by Meridian Medical Technologies in St. Louis Missouri, USA.

Alphapharm is undertaking this recall as a precautionary measure and has patient safety as its first priority.

Instructions to consumers who have an EpiPen® Auto-Injector:

1. **Check if you have a 300 µg EpiPen® (yellow carton and label) and if you do, check the batch number and expiry. The batch number and expiry can be found on the label of the pen or on the end of the carton.**



2. **If your EpiPen® 300µg has the following batch numbers 5FA665, 5FA6651, 5FA6652 or 5FA6653 and an expiry of Apr 17, you need to replace it with a new one as soon as possible by returning to your pharmacist.**
3. **Your pharmacist will replace the EpiPen® 300µg from the affected batch with an EpiPen® 300µg from a different batch FREE OF CHARGE.**
4. **You must keep your current EpiPen® until you get a replacement and use it if required.**

At this time, EpiPen® Jr 150µg Adrenaline Injection Syringe Auto-Injectors and all other batches of EpiPen® 300µg Adrenaline Injection Syringe Auto-Injectors are unaffected and are not subject to this recall.