# Important EpiPen® information

Meridian Medical Technologies, a Pfizer company, the manufacturer of EpiPen<sup>®</sup> and Mylan, the distributor of EpiPen<sup>®</sup>, routinely study and evaluate real-world data about how healthcare professionals, patients and carers administer EpiPen<sup>®</sup>, which is a critical life-saving device.

On 24 March 2020, Pfizer and Mylan published a <u>notification</u> in the US about a very limited number of cases in which the administration of EpiPen<sup>®</sup> 0.3 mg and EpiPen Jr<sup>®</sup> 0.15 mg Auto-Injector, may potentially be delayed or prevented.

The information in this notification serves as an important opportunity to provide precautionary handling instructions and remind people with severe allergy and their carers about the correct administration of EpiPen®, and recommendation to carry two EpiPen® or EpiPen® Jr Auto-injectors at all times.

#### Potential issues and user errors identified are:

## 1. Device failure from activation caused by sideways force to remove blue safety release

In New Zealand there have been no reports of such device failure. The advice in New Zealand is to hold the EpiPen® in one hand (fist around the device) and remove the blue safety release with the other hand. Removing the blue safety release using sideways forces may activate the EpiPen® prematurely.

To prevent this premature activation, patients and their carers should follow the clear instructions on how to use EpiPen<sup>®</sup>.



Please see the How to Use EpiPen<sup>®</sup> video on the EpiClub<sup>®</sup> home page.

# 2. Device failure from inadvertent or spontaneous activation due to raised blue safety release

### In a very limited number of cases, EpiPen<sup>®</sup> devices may have a blue safety release that is slightly raised.

The function of the blue safety release is to ensure the device does not activate prior to its intended use. It should not be removed until the time of use. If the blue safety release is raised the device may activate prematurely, which could potentially delay or prevent emergency treatment when needed.

# If the blue safety release is raised, the auto-injector should NOT be dispensed or used, since premature activation may occur.

Internal testing has shown that the probability of a raised blue safety release at 4.6 mm (as shown in the left picture below) resulting in spontaneous activation is 4 units in 1 billion.



If you have an EpiPen<sup>®</sup> and the blue safety release is raised, contact Mylan NZ on **0800 579 811** to obtain a replacement device at no additional cost. Return the device to the carrier tube and close the lid. Do not attempt to force the blue safety release back down.

### 3. Difficulty removing EpiPen® from the carrier tube

EpiPen® marketed in New Zealand is labelled and packaged in Australia using a different packaging process.

### 4. Certain identified use errors

The issues identified in the US are not relevant in New Zealand because administration guidelines in New Zealand do not recommend the swing and jab technique.

