IRISH MEDICINES BOARD

# Notice Information: - Advisory
# 23 May 2012

## Part 1. Product Information

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| a) | Title: | Anapen Range of treatments for Acute Allergic Reactions – Important Information for Users and Healthcare Professionals |
| b) | Product Name/Type: | Anapen 300 micrograms, Anapen 500 micrograms and Anapen Junior 150 micrograms |

## Part 2. Target Audience

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| a) | Target Audience: | • Users of Anapen<br><br>• Healthcare Professionals – Pharmacists, GPs, Emergency Medicine Doctors, Dermatologists, Immunologists |

## Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) wishes to inform users and healthcare professionals that the Anapen range of treatments for acute allergic reactions will continue to be available to Irish patients. This follows a decision in the UK to initiate a voluntary recall of this product range in the UK. The UK recall is precautionary and is to patient level.

The issue relates to a potential problem with the dose delivery time and delivery volume following activation of the auto-injector. This was observed only in a very small number of units during recent development work on the product. This could result in a failure to deliver some or all of the adrenaline in an emergency situation. The manufacturer has informed the medicines regulatory agency in the UK that they have received no defect or adverse reaction reports from the UK market which may be associated with this issue. The IMB has also received no reports to date from patients or the medical profession in Ireland in connection with this issue.

The UK market has a number of other similar products licensed and available to patients in the absence of Anapen. Following confirmation that sufficient replacement stocks were available in the UK, it was decided to progress to a recall in the UK.

However, Anapen is the main product in the Irish market and, at this time, there is no alternative product that could provide sufficient replacement stock if Anapen was removed from the market. The concern of the IMB is the protection of Irish patients and, accordingly, Anapen will continue to be available until such time as there is an alternative. Patients would be at greater risk if no product was available.

The IMB has carried out a risk assessment for the Irish market and at this time is permitting this product to remain on the Irish market until an alternative product, in sufficient quantities, is available for users. Until there are sufficient stocks of an alternative product available, the risk presented by the defect can be reduced by always carrying two pens, as explained below.

The IMB is in continued discussions with the alternative supplier of licensed adrenaline pens in Ireland and is working with this company to obtain an estimated timeline for the supply of sufficient quantities of rep

replacement stock. The IMB has also reviewed the situation with respect to the availability of unlicensed adrenaline pens. At this time, it cannot be assured that there are sufficient quantities of any unlicensed adrenaline pen product available to meet patient requirements in Ireland.

Advice to Patients

The advice to patients in Ireland is to adhere to current medical advice that they carry two pens. The package leaflet supplied with Anapen advises patients that, in circumstances where a single dose of adrenaline does not completely reverse the effect of an allergic reaction, a repeat injection may be given after 10 to 15 minutes. For this reason, it is important for users to always carry two pens with them at any one time. Please see the package leaflet supplied with your pens for full information on how to safely use this product.

Anapen is indicated as an emergency supportive therapy and the IMB reminds patients of the need to seek immediate medical attention following administration. It also recommends that patients with any concerns in relation to this matter should consult their doctor or pharmacist.

Advice to Healthcare Professionals

Healthcare Professionals should be aware of the information in this Advisory Notice and they are requested to re-iterate to patients the importance of reading the package leaflet for Anapen. The package leaflet supplied with these pens advises patients that, in circumstances where a single dose of adrenaline does not completely reverse the effect of an allergic reaction, a repeat injection may be given after 10 to 15 minutes. For this reason, it is important for users to always carry two pens with them at any one time.

Hospital Pharmacists are asked to please bring the information in this Advisory Notice to the attention of other relevant Healthcare Professionals within their hospital.

## Part 4. Background Information

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| a) | Background Information: | The Anapen range available on the market in Ireland consists of three strengths - Anapen Junior (150mcg), Anapen 300mcg and Anapen 500mcg and is indicated for emergency treatment of acute allergic reactions (anaphylaxis).<br><br>• Anapen 300 micrograms in 0.3ml solution for injection in a pre-filled syringe, PA 1072/1/2<br><br>• Anapen 500 micrograms in 0.3ml solution for injection in a pre-filled syringe, PA 1072/1/3<br><br>• Anapen Junior 150 micrograms in 0.3ml solution for injection in a pre-filled syringe, PA 1072/1/1 |

## Part 5. Enquiries

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| a) | All enquiries should be made to: | The IMB will closely monitor the situation and is in ongoing discussions with alternative suppliers. It will provide updates on its website, www.imb.ie , as appropriate in relation to this matter. |

## Part 6. Keywords

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| a) | Keywords: | Anapen Range of treatments for Acute Allergic Reactions – Important Information for Users and Healthcare Professionals Anapen 300 micrograms, Anapen 500 micrograms and Anapen Junior 150 micrograms |