

**Notice Information: - Recall  
27 February 2014**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Active Substance:
- d) Reference:

e) Serial/Batch Number & Expiry Date:

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Product

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Batch Number

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Expiry Date

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Jext 150mcg

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31/03/2015

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28/02/2015

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31/01/2015

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Jext 300mcg

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31/01/2015

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f) Product Classification:

Prescription-only Medicine

g) Authorisation Number:

PA1255/6/1 & PA1255/6/2

h) Authorisation Holder: ALK-Abelló A/S,  
Horsholm,  
Denmark

i) Prescription Required: Yes

j) Recall Classification: Wholesale, pharmacy and patient level.

## Part 2. Target Audience

a) Target Audience: Patients, carers, healthcare professionals, wholesalers.

## Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) today confirms that it is working with the Marketing Authorisation Holder, ALK-Abello A/S, to ensure the recall of seven batches of the Jext adrenaline autoinjector, in Ireland.

The reason for the recall is that a small percentage (average 0.04%) of autoinjectors from the above-listed batches may not function correctly and lead to injection failure.

The seven batches of Jext 150mcg and Jext 300mcg have been distributed to pharmacies and patients in Ireland and recall letters were issued by the Marketing Authorisation Holder, ALK-Abelló, to wholesalers, pharmacies and general practitioners on 27th February, 2014.

The batches were distributed in Ireland from 6th June 2013, onwards.

## Part 4. Action to be taken

a) Action to be taken:

Information for Patients / Carers

Pharmacists have been asked to contact their patients, to ensure the return of any units from the above-listed batches.

If you have not yet been contacted, please check the batch number of all Jext pens in your possession and in other locations.

If you are in possession of a pen from an affected batch, please return it to your pharmacy where you will receive a replacement, unaffected pen.

If you are in possession of a pen with a batch number not listed above, you can continue to carry that pen as usual

Specific Information for Pharmacists

All pharmacists registered in Ireland have been sent a recall letter via email on February 27th 2014, which details the steps to be taken to ensure an effective recall to pharmacy and patient level can occur. The letter is available at the below link.

[Jext Patient Level Recall.pdf](#)

Information for Prescribers and other Healthcare Professionals

The relevant healthcare professionals have been sent a letter by ALK-Abelló on 27th February 2014, to inform them of the recall and to provide information which can be shared with patients, should they have concerns regarding the recall. This letter is available at the below link.

[Jext Ireland Doctor recall letter.pdf](#)

[Specific Information for Wholesalers](#)



Jext Ireland Doctor recall letter.pdf

Specific Information for Wholesalers

Wholesalers which received the above-listed batches have also been sent a recall letter on February 27th, 2014; a copy of which can be found at the below link

Jext Ireland Wholesaler recall letter.pdf

## Part 5. Enquiries

- a) All enquiries should be made to:

Further information is available at the following link

<http://www.jext.ie>