

27th February 2014

ALK-Abelló Ltd 1 Manor Park Manor Farm Road Reading Berkshire RG2 0NA United Kingdom

T +44 (0)118 903 7940 F +44(0)118 903 7941 W alk-abello.com/uk

Batch Recall Jext 150mcg Solution for Injection in a Pre-filled Pen PA1255/6/1 Jext 300mcg Solution for Injection in a Pre-filled Pen PA1255/6/2

| Product | Batch Number | Expiry date |
|-------------|--------------|-------------|
| Jext 150mcg | 0000884201 | 31/03/2015 |
| | 0000871645 | 28/02/2015 |
| | 0000785382 | 31/01/2015 |
| Jext 300mcg | 0000874584 | 28/02/2015 |
| | 0000816025 | 31/01/2015 |
| | 0000774776 | 31/01/2015 |
| | 0000780783 | 31/01/2015 |

Dear Wholesaler

ALK-Abelló wishes to advise you that the above-listed batches of Jext 150mcg and Jext 300mcg auto-injectors are being recalled with immediate effect.

The recall is going to patient level.

This action has been agreed with the Irish Medicines Board.

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

Please immediately quarantine any units of these batches which you have in your possession and return them to United Drug, Dublin, for credit, within four weeks of receipt of this recall letter.

Please anticipate return of stock from retail pharmacies for credit following receipt of this recall letter. Replacement, unaffected stock is currently available at United Drug. Do not contact your pharmacy customers, as United Drug is uplifting stock from pharmacies directly.

If you have supplied these batches to any other wholesaler, please fax those wholesalers a copy of this recall letter, requesting that they quarantine and return any unsold quantities of these batches to you.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact ALK-Abelló at +44 118 903 7940.

Yours sincerely

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Dr Stephen Lombardelli Medical Director