

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 Pharmacist

Following previous communications from the Irish Medicines Board / ALK-Abelló on 6th December 2013, 20th December 2013, 16th January 2014 and 26th February 2014, 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 can now happen as replacement, unaffected, Jext pens are currently available at wholesalers.

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.

If you have identified and quarantined units for return, please detail those units on the attached fax-back form and send it to United Drug at the number included, so that they can be uplifted. Please fill out and return the fax-back form, regardless of whether or not you possess any pens from the above-listed batches. The last date by which recalled stock on your premises will be received back for credit is two weeks from the date of receipt of this recall letter.

We kindly request that the following instructions are followed and disseminated as appropriate:

1. Please endeavour to contact those patients or carers to whom Jext has been dispensed since 6th June 2013 (please note that this is the date on which units from impacted batches were first distributed in Ireland) to ascertain if they are in possession of a pen / pens from any of the above-listed batches. Please relay the following requests to the patient / carer:
 - Please check your home and other relevant locations, including schools and workplace, to identify all Jext pens in your possession
 - Please check the batch number on the pens, labels or outer cartons, to ascertain if you are carrying any pens from the affected batches
 - If you are carrying pens from an affected batch, please return them to the pharmacy or clinic from which they were received, where you will be given replacement, unaffected pens
2. Please ensure that the requisite number of pens is ordered from your wholesaler, to replace all pens returned by your patient(s)
3. When the patient returns the pens to you, please contact United Drug to arrange for uplift, as detailed on the fax-back form
4. If you have distributed units from these batches to a GP, clinic, another pharmacy or any other party, please contact them so that they may return the units to you.

For Hospital Pharmacists only:

Please be advised that units on wards, in ambulances and in any other location in your hospital should also be recalled. Please forward this communication to the relevant healthcare professional(s) in those locations, so that pens from the affected batches may be identified and returned 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



Dr Stephen Lombardelli
Medical Director

UnitedDrug
Distribution



UNITED DRUG FAX BACK FORM

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]

Pharmacy Name	
Telephone Number	

The below form should be completed and returned to United Drug Supply Chain Services **immediately** at **Fax Number 01 +353 1 463 2373 or 01 +353 1 463 2404**

Should the fax fail please phone the United Drug Quality Department at 01 463 2300.

Please fill in the below table, **even if you do not have any units of the below-referenced batches**

Product	Batch	Quantity quarantined
Jext 150mcg Solution for Injection in a pre-filled pen [PA 1255/6/1]	0000884201	
	0000871645	
	0000785382	
Jext 300mcg Solution for Injection in a pre-filled pen [PA 1255/6/2]	0000874584	
	0000816025	
	0000774776	
	0000780783	

These units will be directly uplifted from your pharmacy by United Drug, they should not be returned by you to your wholesaler. Please retain the original copy of this fax-back form to be returned with the affected units.

Should any further units be returned from patients to your pharmacy please contact the **Quality Department at 01 463 2300** to advise on quantities returned and to organize uplift of the units with the aim of having all units returned by the **31st March 2014**.

Please sign below indicating that you have read and understood the recall notification and that the quantities indicated by you in the table above are accurate as on the date signed below.

Pharmacist Name (Print)	
Pharmacist Name (Sign)	
Date	
Time	

Pharmacy Stamp
