

## Annex 4 Letter to Healthcare Professionals

Dear Healthcare Professional

### Extended Use Beyond Labelled Expiry Date for Selected Lots of Jext® 150 mcg and 300 mcg Adrenaline Auto-Injectors

This letter is sent in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) to inform you of the following:

To ease the current shortage of adrenaline autoinjectors, ALK has obtained acceptance from the MHRA to extend the use of specific lot (batch) numbers of Jext® 150 mcg and Jext® 300 mcg auto-injectors, beyond the labelled expiry date by four months. The affected lot numbers are listed in the table below and are also available on [www.jext.co.uk](http://www.jext.co.uk).

**Table 1 Affected lots (batches) for extended use of Jext® auto-injectors**

No.	Strength, mcg	Lot (batch) no.	Labelled Expiry Date (end of the month)	Extended Use by Date (end of the month)
1	150	T4933	Jul 2018	Nov 2018
2	150	T5019	Aug 2018	Dec 2018
3	150	T5132	Aug 2018	Dec 2018
4	150	T5326	Sep 2018	Jan 2019
5	150	T5407	Sep 2018	Jan 2019
6	150	T5478	Sep 2018	Jan 2019
7	150	T5669	Oct 2018	Feb 2019
8	150	T5819	Oct 2018	Feb 2019
9	150	T5940	Oct 2018	Feb 2019
10	150	T6143	Nov 2018	Mar 2019
11	150	T6399	Nov 2018	Mar 2019
12	150	T6620	Nov 2018	Mar 2019
13	150	T9630	Dec 2018	Apr 2019
14	300	T4801	Jul 2018	Nov 2018
15	300	T4857	Jul 2018	Nov 2018
16	300	T5122	Aug 2018	Dec 2018
17	300	T5327	Sep 2018	Jan 2019
18	300	T5401	Sep 2018	Jan 2019

No.	Strength, mcg	Lot (batch) no.	Labelled Expiry Date (end of the month)	Extended Use by Date (end of the month)
19	300	T5468	Sep 2018	Jan 2019
20	300	T5656	Oct 2018	Feb 2019
21	300	T5779	Oct 2018	Feb 2019
22	300	T5747	Oct 2018	Feb 2019
23	300	T5798	Oct 2018	Feb 2019
24	300	T5867	Oct 2018	Feb 2019
25	300	T6074	Nov 2018	Mar 2019
26	300	T6233	Nov 2018	Mar 2019
27	300	T6366	Nov 2018	Mar 2019
28	300	T6363	Nov 2018	Mar 2019
29	300	T6554	Nov 2018	Mar 2019
30	300	T6721	Nov 2018	Mar 2019
31	300	T6635	Dec 2018	Apr 2019
32	300	T6846	Dec 2018	Apr 2019

**Important: the extended use only applies to the lots of Jext® 150 mcg and Jext® 300 mcg auto-injectors listed above. Patients can continue to use the Jext® auto-injectors of these specified lots safely until the extended use by date as stated above.**

**This extended use does not apply to any other lot number of Jext® autoinjectors not specified. Patients must continue to adhere to the labelled expiry date on any Jext® autoinjector not covered by the lot numbers above.**

#### **Further information on the extended use of the listed lots of Jext® autoinjectors**

There is currently a shortage of adrenaline auto-injectors in the UK. This shortage has been caused by intermittent supply issues of the most commonly prescribed brand and is affecting most countries in Europe. It is anticipated that supply will stabilise in the fourth quarter (October to December) of 2018. The supply status will be continuously reviewed by the Department of Health and Social Care.

ALK is working hard to help address the situation and has significantly increased production of its Jext® 150 mcg and 300 mcg adrenaline auto-injectors at its European manufacturing facility. However, due to the time needed for manufacture and the magnitude of the current deficit, it is not possible for ALK to completely meet the shortfall in supply in the short term.

To further ease the shortfall, the period that 32 specific lots of Jext® 150 mcg and Jext® 300 auto-injectors (listed above) can be used has been extended by 4 months beyond the labelled expiry date on the pack.

Lot numbers and labelled expiry dates are marked on the side of the box and on the autoinjector label itself.

This extended use of 4 months beyond the labelled expiry date for the specific lots is based on supportive stability data for Jext® autoinjectors and has been reviewed by the MHRA. The Jext® autoinjectors of these specific lots will continue to work safely and as intended within the allowed extended use by date. The Jext® autoinjectors should continue to be stored as labelled on the pack.

At the end of the extended use period (the end of the month listed in the right column of the table above), a new autoinjector will still need to be obtained.

### **Further information on recommendations to healthcare professionals**

- Tell patients and caregivers about the extended use by date of the specified lots of Jext® 150 mcg and 300 mcg autoinjectors as listed above. This does not apply to other lots of Jext® autoinjectors not listed.
- Show patients and caregivers where to find the lot numbers on their device (on the side of the box and if necessary, on the device label itself) and encourage them to sign up for the Expiry Alert Service.
- Reassure patients and caregivers that their device will continue to work safely over the extended use period.
- Remind patients and caregivers that they should still obtain a new device near the end of the extended use period.
- Advise patients to continue to check periodically the viewing window in the label of their device to ensure the liquid inside is clear and colourless. Do not use the device if the liquid is discoloured.

This announcement regarding the extended use of certain batches supersedes any notification that a patient may receive via the expiry alert service from [www.jext.co.uk](http://www.jext.co.uk). If you require additional information or have any questions, please contact ALK Customer Services: **0118 903 7940**.