Pharmacy and Dispensing Practice Q&A regarding EpiPen and EpiPen Junior Supply issue- document updated on 5/11/2018 in line with the 'Revised - 150microgram adrenaline auto injector validation protocol'

Why is there a supply issue affecting EpiPen and EpiPen Junior?

You will be aware following the recent DHSC Supply Disruption Alerts about supply issues affecting EpiPen and EpiPen Junior adrenaline auto-injectors (AAIs), see link to the latest alert. https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102802

There has been an ongoing supply issue affecting EpiPen (a Mylan product) for several months. The issue is due to manufacturing delays from Mylan's contract manufacturer, Meridian Medical Technologies, a Pfizer company in the US. Stabilising supply is taking longer than anticipated and is affecting countries globally. Initially the delays affected the 300microgram preparation of EpiPen, however these have recently been extended to the EpiPen Junior 150microgram device where the situation is now most acute.

Are the suppliers of the alternative device aware of the shortage?

In the UK there are two alternative adrenaline auto-injector devices available, Emerade, supplied by Bausch and Lomb and Jext, supplied by ALK. Both companies manufacture adult and paediatric presentations of adrenaline auto-injectors are aware of the supply disruptions affecting EpiPen and EpiPen Junior and are working with their supply chains to increase supplies to the UK for the remainder of this year.

What is the current supply position and can the other suppliers meet the shortfall?

EpiPen Junior 150microgram is currently available from wholesalers and further supplies are expected at the end of November. Supplies of Jext 150microgram and Emerade 150microgram are currently available and further supplies are expected during November. It is anticipated there will be a backlog of patients requiring new devices from August, September and October, so supplies may be constrained until the end of the year.

Supplies of EpiPen 300microgram are currently available, but constraints are anticipated to continue for the coming months. Supplies of Jext 300microgram, Emerade 300microgram and 500microgram are currently available. Across all three brands, available supplies of the 300microgram and 500microgram devices are in line with historic usage requirements, but patients may be prescribed an alternative device to the one they are normally on and may require support/training with using this new device. Some older children (over 25kg) may have been moved onto a 300microgram device to conserve supplies of the 150microgram devices; they may also have been switched to an alternative brand at the time of up-dosing and will similarly require support/training.

Why has the prescription validation process changed?

As there has been a supply issues affecting EpiPen Junior since August, there may still be a backlog of patients requiring new devices. Therefore, children weighing 25kg or less with the greatest short-term need must still have access to junior devices first. The previous validation protocol required pharmacies and dispensing practices to 'validate' with the patient or their carer at the time they present with a prescription for a 150microgram adrenaline auto injector to deduce whether the prescription should be fulfilled, partially fulfilled, or supply delayed. The purpose of this protocol was to ensure that every eligible patient had access to at least one in-date device and to avoid a situation whereby some patients were able to access two in-date devices, whilst others had none. As the stock position is now improving, the available supplies

should be sufficient to ensure that every patient has at least two in date 150microgram adrenaline auto injectors. However, stocks are not sufficient to allow more than two pens to be supplied so the Pharmacy dispensing validation process must still remain in place but this has now been partially relaxed to allow patients to receive a maximum of two pens.

What have I got to do?

Dispenser validation protocol- Pharmacies and dispensing practices will still need to 'validate' with the patient or their carer at the time they present with a prescription for a 150microgram adrenaline auto injector, but they should use the 'Revised - 150microgram adrenaline auto injector validation protocol' to deduce whether the prescription should be fulfilled, partially fulfilled, or supply delayed. The purpose of the validation is to ensure that every eligible patient has two in-date devices.

Prescription validation- If the pharmacist on carrying out the above 'dispenser validation protocol' considers that at least one or two devices need to be supplied, it is likely they will have to order the supply from their wholesaler. The wholesalers will continue to have the process known as 'prescription validation' in place, which includes having to send an image of the prescription with ***all*** the patients details carefully obscured or a unique identifier number to their wholesaler. The wholesaler will be able to provide further details about this process. Please remember that all images will need to be accompanied with the pharmacy's account number and trading name. Wholesalers have been informed about the change in practice and are aware that two devices can be issued.

What do I do if I only partially fulfil a prescription?

If as part of the dispenser validation process you only partially fulfil the prescription, please tell the patient that you are not able to give them the full supply but this prescription will be 'closed' and they will need to return to their GP to get a new prescription, when they no longer have 2 devices or when the supply issue eases. You can reassure the patient that this is a national ruling and applies equally to all patients in the same position as themselves – it is to ensure that nobody is left without any devices at all. Endorse the prescription clearly with the quantity supplied and submit the prescription to the NHS BSA in the normal way.

If we were only able to partially dispense a prescription in October, can we now fulfil the full amount?

For those prescriptions that were partially dispensed in October using the original protocol, these should have already been marked 'closed' with the quantity supplied clearly marked and sent to the BSA. DO NOT try to use them to get a further supply for this patient from the wholesaler, as the wholesaler will identify that they have seen the prescription before and decline a supply. The patient will now need to get a new prescription to obtain any further supplies.

How long will all this take?

It will of course take a little longer to dispense these prescriptions for patients, but this is justified to ensure these lifesaving medicines are reserved for patients who urgently need new supplies.

Why do community pharmacies have to do this?

All of the supply chain and the NHS is having to play a part in managing this situation. For example, GPs are being asked to send patients a patient letter and ensure that they only prescribe for patients without any adrenaline auto injector at all, or whose devices have expired.

However, there may be patients who already have a prescription or repeat prescriptions for more than two devices in the system that were written before the shortage was clear. Pharmacists and their staff will have their own relationship with patients and knowledge of a patients' situation so that they can help them to carry out the dispenser validation process.

How long will I have to do it for?

Further deliveries all of three auto-injectors are expected during November, but there may be ongoing constraints until the end of this year. The process will therefore remain in place until there are sufficient supplies to meet demand. We will communicate again when restrictions can be fully or partially lifted.

However, once this process is no longer required it may be possible that some restrictions on supply will remain in place at wholesaler level.

Do I need to do this for all adrenaline auto-injector devices or just EpiPen Junior?

Yes - the process applies to all 150microgram adrenaline auto-injector devices, irrespective of brand

Do I need to do this for the higher strength (300microgram and 500microgram) adrenaline autoinjector devices?

The pharmacy validation process only applies to EpiPen Junior 150microgram, Jext 150microgram and Emerade 150microgram adrenaline auto-injectors.

The pharmacy validation process **does not** apply to EpiPen 300microgram, Jext 300microgram, Emerade 300microgram, or Emerade 500microgram adrenaline auto-injectors. However, wholesalers will continue to implement any management process that they have already had in place for these devices.

Won't the GP already have asked the patient these things?

It is possible that patients have already been asked these questions, but it is important that we ensure all patients (or carers) are asked before a supply is made. Prescribers and pharmacists should work together to ensure that those patients with the greatest short-term need have priority access to the 150microgram adrenaline auto-injectors as they become available.

Will there be extra money for doing it?

Prescriptions dispensed will be reimbursed in the normal way. All the supply chain and the NHS will be bearing extra work to manage this situation, however it is expected that it will be managed within existing resources.

Isn't it unethical not to dispense the full amount on the prescription?

GPhC are aware of this issue and recognise that this process is being put in place in an unusual situation to ensure that those patients that have a clinical need to receive a supply do so. It is important that pharmacists use their professional judgement and act in the best interests of the patient, and should contact the prescribers to discuss where appropriate.

How will I know I no longer have to do it?

We will use the same communication channels to let pharmacies know that the 'validation' protocol no longer needs to be used and that full quantity requested on prescriptions can be dispensed as they are presented.

Have any of the 150 microgram adrenaline auto-injectors received approval from the MHRA for extended use beyond the labelled expiry date?

EpiPen Junior 150microgram Adrenaline Auto-Injectors:
Mylan UK have obtained acceptance from the MHRA to extend the use of specific batch numbers of EpiPen 300microgram auto-injectors, beyond the labelled expiry date by four months. Further information about the affected lot numbers can be found on the EpiPen website http://www.epipen.co.uk/

Department of Health Chief Pharmacists letters about this have already been circulated to health professionals. The extended use only applies to the lots of Epipen 300microgram auto-injectors listed

above. This extended use does not apply to EpiPen 150microgram auto-injectors or any lot number of Epipen 300microgram auto-injectors not specified.

Jext 150microgram Adrenaline Auto-Injectors
ALK has obtained acceptance from the MHRA to extend the use of specific lot (batch) numbers of Jext 150 microgram and Jext 300 microgram 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.

A DHCP letter with further information about this and the specific batch numbers is included in Annex 1.

Emerade 150microgram Adrenaline Auto-Injectors
Bausch and Lomb have not obtained acceptance from the MHRA to extend the use of any lot (batch) numbers of Emerade 150 microgram or Emerade 300 microgram auto-injectors.

Annex 1 ALK Letter to Healthcare Professionals

16th October 2018

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 auto injectors, 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.

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	T6930	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® auto injectors not specified. Patients must continue to adhere to the labelled expiry date on any Jext® auto injector not covered by the lot numbers above.

Further information on the extended use of the listed lots of Jext® auto injectors

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 auto injector 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® auto injectors and has been reviewed by the MHRA. The Jext® auto injectors of these specific lots will continue to work safely and as intended within the allowed extended use by date. The Jext® auto injectors 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 auto injector 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 auto injectors as listed above. This does not apply to other lots of Jext® auto injectors 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. If you require additional information or have any questions, please contact ALK Customer Services: **0118 903 7940**.

Yours sincerely

Sean Connor
General Manager
UK, Ireland and Benelux