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Pharmacy and Dispensing Practice Q&A regarding EpiPen and EpiPen Junior Supply issue

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 (AAs), 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?

Mylan are currently out of stock of the EpiPen Junior 150microgram and further supplies are not expected until the end of October. Further supplies of Jext 150microgram and Emerade 150microgram are expected to be made available at UK wholesalers during the w/c 15th October, but it is not foreseen to be sufficient to fulfil normal demand. In addition, it is anticipated there will be a backlog of patients with prescriptions to be dispensed from August and September.

Further deliveries of all three 150microgram auto-injectors are expected during November, but there may be ongoing constraints until the end of this 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 have I got to do anything different before dispensing a prescription?

Dispenser validation (see below) of 150microgram auto-injectors is necessary to ensure there is supply for those with the greatest immediate need i.e. those patients without any adrenaline autoinjector at all, or whose device has expired.

What have I got to do?

Dispenser validation protocol - Pharmacies and dispensing practices need to 'validate' with the patient or their carer at the time they present with a prescription for a 150microgram adrenaline auto injector. See '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 at least one in-date device and that a situation is avoided where some patients have two in-date devices, whilst others have none. This does mean that many patients will have to carry one in-date pen and one expired pen; we are aware of this and clinical experts have agreed this advice until the shortage eases.

Prescription validation- If pharmacist on carrying out the above 'dispenser validation protocol' considers that at least one device needs to be supplied, it is likely they will have to order the supply from their wholesaler. The wholesaler will have a process known as 'prescription validation' in place, which will include 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 and for prescriptions for more than 1, they will need to confirm whether they need 1 or 2 devices, before the wholesaler will send the order.

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 prescription for another one, when they no longer have 2 devices or when supply 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.

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 have none.

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 the patient letter (see attached) and ensure that they only prescribe for patients without any adrenaline autoinjector at all, or whose device has expired.

However, there may be patients who already have a prescription or repeat prescriptions 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 a prescription?

By not immediately dispensing to those who have a usable device enables supply to be reserved to those with the greatest need, and reduces the risk that some equally needy patients will have nothing

As supplies return to normal we expect all prescriptions to be dispensed in due course.

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 all 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/>

DHCPs 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

Dear Healthcare Professional

Extended Use Beyond Labelled Expiry Date for Selected Lots of Jext® 150 microgram and 300 microgram 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 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.

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

| No. | Strength, microgram | 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 |

| No. | Strength, microgram | Lot (batch) no. | Labelled Expiry Date (end of the month) | Extended Use by Date (end of the month) |
|-----|---------------------|-----------------|---|---|
| 16 | 300 | T5122 | Aug 2018 | Dec 2018 |
| 17 | 300 | T5327 | Sep 2018 | Jan 2019 |
| 18 | 300 | T5401 | Sep 2018 | Jan 2019 |
| 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 microgram and Jext® 300 microgram 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 microgram and 300 microgram 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 microgram 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 end-flap 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 microgram and 300 microgram 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 end-flap 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**.