Mounjaro®▼ (tirzepatide) 2.5 mg KwikPen®: batch-specific shelf-life extension

Pharmacy FAQ Document

1. What is the background for this update?

On 25th March 2024, the Mounjaro KwikPen SmPC was updated to include an extension to the shelf life for the KwikPen, increasing it from 9 months to 14 months following the validation of new product stability data by the MHRA. This extension applies to all new stock produced, as well as to stock already in the country as detailed below.

On the 8th April 2024, following this shelf-life extension approval, Lilly and the MHRA agreed on a batch-specific variation (BSV) to apply to the shelf-life of the 2.5 mg KwikPens currently available in Great Britain. This means that the specific batches D712074, D720751 and D720957 of Mounjaro 2.5mg KwikPen now have a 14-month shelf-life. There are no safety concerns related to these Mounjaro KwikPen batches.

As a result, a direct to healthcare professional (DHPC) and patient letters have been approved by the MHRA for dissemination to inform these groups of this variation approval and specific guidance for implementation.

2. What batches of Mounjaro 2.5 mg KwikPen are affected?

Affected batches for extended use of Mounjaro® 2.5 mg KwikPen®:

Product	Batch Number	Displayed/Printed Expiry Date (MM-YYYY)	New Expiry Date (MM-YYYY)
Mounjaro® 2.5mg KwikPen® solution for injection in pre-filled pen	D712074	05-2024	10-2024
Mounjaro® 2.5mg KwikPen® solution for injection in pre-filled pen	D720751 D720957	09-2024	02-2025

NB: Lilly's warehouse operates on a first in first out basis, so batch D712074 with new expiry date 10-2024 will be available first on the market, to be replaced by batches D720751 and D720957 (with new expiry 02-2025) after expiry or all units of batch D712074 have been sold.

3. What does this mean for packs of Mounjaro 2.5 mg KwikPen from these affected batches?

Specific units of batches D712074, D720751, and D720957 that are **still under Lilly's control at our local warehouse** will not be re-labelled, but will be inserted into a clear plastic bag with a letter advising patients to follow the below indicated New Expiry Date for these batches. This is expected to be in place from early May 2024.

Units from these three batches that have **already been released onto the market** will not be customized, but the patient letters have been made available to be provided to patients who receive these batches.

From 6th May, all stock from these batches will be distributed by Lilly and their Logistics Service Providers, AAH and Phoenix, with this letter for patients to read at the point of dispensing.

4. How has this update been communicated?

As part of the approved communication plan aligned with Lilly and the MHRA, a direct to healthcare

professional letter (DHPC) and 2 patient letters have been approved for dissemination to inform these groups of this approval and provide reassurance about the validity of the product. These letters have been communicated out via a number of channels to ensure that the relevant groups are informed. These include Lilly-owned communication channels (such as hard copy delivery by field representatives and mass email), logistic service providers (AAH and Phoenix Healthcare Distribution) who deliver Lilly medicines, third party mass email sends and notification of patient organisations.

Lilly medical information will be available to respond to any patient queries received on this subject.

5. Where do I signpost any patients concerned about the expiry dates?

The MHRA have approved patient letters detailing the updated expiry dates for each affected batch of Mounjaro 2.5 mg KwikPen. From 6th May, all stock from these batches will be distributed by Lilly and their Logistics Service Providers, AAH and Phoenix, with this letter for patients to read at the point of dispensing.

These letters will also be made available via the Lilly Diabetes & Obesity website.

6. The current batch shows as expired stock, is it still safe for patients to use the product?

Mounjaro was validated with new stability data to support an extension of shelf life from 9 months to 14 months, which the MHRA has approved on 25-Mar-2024.

On the 8th April 2024, following this shelf-life extension approval, Lilly and the MHRA agreed on a batch-specific variation (BSV) to apply to the shelf-life of the 2.5 mg KwikPens currently available in Great Britain. This means that the specific batches D712074, D720751 and D720957 of Mounjaro 2.5mg KwikPen now have a 14-month shelf-life. There are no product quality, safety or efficacy concerns related to the affected Mounjaro® 2.5mg KwikPen® batches.

More details can be found via the Dear HCP Letter for this update, which has been approved by the MHRA.

7. With the new shelf-life extension, does this affect the storage requirements if the product is kept outside of the fridge?

No – storage requirements are consistent with the Mounjaro KwikPen SmPC which is unaffected by this update, as follows:

Store in a refrigerator (2 ° C – 8 ° C).

Do not freeze.

Mounjaro may be stored unrefrigerated for up to 30 days at a temperature not above 30 ° C and then the pre-filled KwikPen must be discarded.

8. If a patient refuses to accept short-dated stock/expired stock, can a pharmacy request credit or replacement stock from the wholesaler or manufacturer?

Replacement or credit is only granted by Lilly after a legitimate product complaint has been investigated and upheld. Unless there is a fault with the device, these will not be granted for refusal due to the printed expiry date alone, as the new date should be considered in line with the approval of this specific variation.

All available Mounjaro 2.5 mg KwikPen stock in the UK is from the 3 batches included in this variation approval. Lilly's warehouse operates on a first in first out basis, so batch D712074 with new expiry

date 10-2024 will be available first on the market, to be replaced by batches D720751 and D720957 (with new expiry 02-2025). These batches will be made available before any subsequent stock is distributed which has an expiry date printed on the label that can be followed.

9. What information or reassurance can pharmacists provide patients concerned about the reduced pen expiry date?

The MHRA have approved patient letters detailing the updated expiry dates for each affected batch of Mounjaro 2.5 mg KwikPen. From 6th May, all stock from these batches will be distributed by Lilly and their Logistics Service Providers, AAH and Phoenix, with this letter for patients to read at the point of dispensing.

These letters have also been available via the Lilly Diabetes & Obesity website.

These letters state that the product can be used in line with the new expiry date, as opposed to the printed expiry date on the carton and pen, as well as that the product of these specific batches will continue to work safely and as intended within the allowed extended use by date.

10. Will packs be over labelled with new expiry dates?

No – packs and pens will continue to show the old expiry date. A re-labelling exercise was explored but this would require all units from these batches to be dispatched from the UK back to the relevant manufacturing site in Italy. This would have a number of potential risks including temperature excursions from registered storage conditions, impact to product integrity (including pre-existing safety features on the product such as the unique identifier and tamper evident seal) as well as impact to continuous supply of this medication in the UK.

Due to the above reasons, alongside the timelines required, this was not a feasible option, and the MHRA has approved this implementation plan and relevant communications.

11. How can a pharmacy identify affected stock?

This approval relates to specific batches of Mounjaro 2.5 mg KwikPen. These can be identified via the batch number on the pen and the carton. The batch numbers are below, and the old/new expiry dates can be found in the summary table included previously as well as the Dear HCP and Dear Patient Letters.

Affected batch numbers:

- D712074
- D720751
- D720957

12. What do pharmacies need to do if the product does not arrive in a plastic bag?

Until 6th May 2025, units of Mounjaro 2.5 mg KwikPen have been distributed without the patient letter, as agreed with the MHRA while Lilly completed the work to customise all remaining packs they have at their warehouses. With or without the letter, units from these batches can still be used in line with the extended expiry date.

For units that are not in a plastic bag with the patient letter, ensure that the patient is supplied with the relevant letter for that batch at the point of dispensing and is made aware of the new expiry date.

Patient letters can be found with this communication and can also be supplied by Lilly, either via their website or via a field representative.

13. Will pharmacies be given additional leaflets to hand out to patients if a patient loses it?

Yes. Patient letters can be found with this communication and can also be supplied by Lilly in digital

or hard copy, either via the Lilly Diabetes and Obesity website or via a field representative.

14. Will wholesaler systems warn pharmacies about short-dated stock at the point of ordering?

Yes. Lilly supplies their medicines to dispensing points through AAH and Phoenix Healthcare Distribution, acting as Logistic Service Providers.

Both of these organisations have been notified of this update and have sent a proactive communication to their dispensing points to inform them. A pop-up banner has also been added to the relevant page for when a pharmacy is looking to order Mounjaro 2.5 mg KwikPen, to inform them of this update.

15. Reminder of reporting information for adverse events and product complaints

Reporting information for HCPs:

Please remind HCPs that adverse events should be reported. Reporting information is contained within the DHPC letter.

Additionally, we recommend the following information is communicated to Mounjaro patients by HCPs:

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.

If you experience side effects, talk to your prescribing healthcare professional. This includes any possible side effects not listed in the package leaflet. To report a side effect or product complaint with a Lilly product please call Lilly UK on 01256 315000. Additionally, reporting forms and further information can be found at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store (UK). By reporting side effects, you can help provide more information on the safety of medicines.