



EMA alerts EU patients and healthcare professionals to reports of falsified Ozempic pens

News 18/10/2023

The European Medicines Agency has been notified by relevant national competent authorities that pre-filled pens falsely labelled as the diabetes medicine **Ozempic** (semaglutide, 1 mg, solution for injection) have been identified at wholesalers in the EU and the UK.

The pens, with labels in German, originated from wholesalers in Austria and Germany.


The pens have batch numbers, 2D barcodes and unique serial numbers from genuine Ozempic packs. In the EU, each medicine pack has a unique 2D barcode and serial number so that it can be tracked in an EU-wide electronic system. When the packs of the falsified Ozempic were scanned, the serial numbers were shown to be inactive, thereby alerting operators to a potential falsification.

There are differences in the appearance between the falsified pen and the original pen. A picture of the falsified pen has been published by the [German medicines agency](#) (please note that the picture of the falsified pen is an example and falsified pens with other features are also likely).

There is no evidence that any falsified pens have been dispensed to patients from legal pharmacies and there are no reports of harm to patients in relation to the falsified medicine.

The issue is currently being investigated by EU medicines regulatory authorities and the police. EMA is assisting national authorities in their investigations. Wholesalers and pharmacies in the impacted countries have been warned about the suspicious offers of Ozempic to wholesalers. In addition, parallel distributors across the EU have been alerted.


In the meantime, the German and Austrian regulatory authorities have issued statements of non-compliance with good distribution practices (GDP) to the concerned wholesalers in their countries for not following required procedures, including compliance with security measures. EMA is monitoring the situation closely and will provide updates as appropriate.

The latest reports of falsification come in the wake of an increase in demand for Ozempic which has also led to a shortage situation. Further information on the shortage can be found in the  [EMA shortage catalogue](#).

Information for patients


- Patients across the European Union (EU) are being alerted to reports that falsified Ozempic pens have been identified at wholesalers in the EU and the UK and further reports cannot be excluded.
- Check the patient information leaflet for Ozempic to see what the genuine Ozempic pens should look like.
- You must not use Ozempic pens that you suspect are falsified as this may lead to serious health consequences.
- If you have a pen that does not show the features of the original pen, return them immediately to your pharmacy and follow advice from your [national medicine agency](#).
- There is no evidence that any affected product has been dispensed to patients from legal pharmacies.
- If you buy medicines online you should only do so from legal pharmacies. For more information, check our website on [buying medicines online](#).

Information for healthcare professionals

- Healthcare professionals across the EU are being alerted to reports of suspicious offers of falsified Ozempic pens. Further cases cannot be excluded.
- Wholesalers and pharmacies are recommended to exercise caution when purchasing Ozempic from suppliers and checking packages in the verification system. Any suspicions should be reported to the [national competent authority](#).
- There is no evidence that any affected product has been dispensed to patients from legal pharmacies. However pharmacists should check the pens when dispensing and should advise patients on how to identify falsified packs (based on the patient information leaflet and the pictures published by the [German medicines agency](#) ). Healthcare professionals should also remind patients to only buy medicines from legal pharmacies (For more information, check our website on [buying medicines online](#)).
- If you have any pens or if patients come to you with pens that match the picture of the falsified pen linked above or do not match pictures of the genuine product, or anything else that may look suspicious, please alert your [national competent authority](#) immediately and follow their advice.

More about the medicine

Ozempic contains the active substance semaglutide and is authorised for the treatment of type 2 diabetes.

An increase in demand for the medicine has led to a shortage which is currently ongoing (for further information, consult the  [EMA shortage catalogue](#)).

Related content

- [Ozempic: EPAR](#)

- [Ozempic: Paediatric investigation plan](#)
- [Ozempic: Paediatric investigation plan](#)
- [Ozempic: Paediatric investigation plan](#)

Related document

-  [Shortage of Ozempic \(semaglutide\)](#)

External links

- [German medicines agency](#) 

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