	Reference Number **NKIS.544.87.2022**

From: Chief Pharmaceutical Inspectorate, Poland		
1. To: (see list attached, if more than one)		
2. Product Recall Class of Defect: **I**		3. Falsification
4. Product: Ozempic®	5. Marketing Authorisation Number: * For use in humans/~~animals~~ (delete as required) EU/1/17/1251/003	
6. Brand/Trade Name: Ozempic®	7. INN or Generic Name: Ozempic®	
8. Dosage Form: injection 0,5 mg/1,5 ml	9. Strength: 0,5 mg	
10. Batch number (and bulk, if different): unknown batch	11. Expiry Date: 06/2025	
12. Pack size and Presentation: box with single vial	13. Date Manufactured: unknown	
14. Marketing Authorisation Holder: Novo Nordisk A/S		
15. Manufacturer†:Novo Nordisk A/S	16. Recalling Firm (if different):	
17. Recall Number Assigned (if available)~~:~~		
18. Details of Defect/Reason for Recall: Novo Nordisk Medical Representative received information about a counterfeit Ozempic product available in Poland. During the visit the doctor informed that her Patient purchased the "Osempik Semaglutide 0,5 mg" product at a fitness club in Warsaw, Poland. The doctor received photos of the product from the Patient and shared them with the NN Med. Representative. The product packaging is in German Language and seems to be produced by Bayer Laboratories. According to investigation on provided pictures it was concluded that product is counterfeit. Novo Nordisk does not market Ozempic (semaglutide) in vials. The secondary packaging and the label misspell the name Osempik and, eventually, Bayer Laboratories are not marketing Ozempic (or Ozempik). As the product is considered to be a counterfeit product, Novo Nordisk higly advise not to use the product, as using it can have severe health consequences.		
19. Information on distribution including exports (type of customer, e.g. hospitals): * Currently unknown, investigation in progress.		
20. Action taken by Issuing Authority: Investigation in progress.		
21. Proposed Action: Further Investigation into the case.		
22. From (Issuing Authority):		23. Contact Person:
24. Signed:	25. Date: 10.09.2022	26. Time: 15:00

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.


für Injektion
KG 3979
6/2025


Ozempik
Semaglutide
0.5 mg


BAYER
LABS
0,5 mg
Bayer Laboratories Gmbh
13342 Berlin
Deutschland
Vor dem Gebrauch soll man die Anweisungen lesen.
Das Arzneimittel vor Kindern schützen.
Bitte lesen Sie folgende Gebrauchsinformation aufmerksam, weil sie wichtige Informationen darüber enthält, was Sie bei der Anwendung dieses Arzneimittels beachten sollen.
Wenden Sie sich bei Fragen bitte an Ihren Arzt oder Apotheker.
Bayer Laboratories