

To Whom It May Concern

04 July 2026

Confirmed Counterfeit of Polivy 140 mg in Iran

Roche Reference: QE-199259

Complaint References: CMP-006097

Dear Sir or Madam,

On 11-May-2026, a suspected counterfeit was reported on behalf of a patient in Mashhad, Iran. The patient acquired a product claiming to be Polivy lyophilized Vials 140 mg from an individual representing a single-prescription import company. Roche received pictures displaying parts of four folding boxes, but no pictures of the vials or leaflets were available. All four boxes displayed the same variable data ("19 11 27 H6980H05") and identical serial numbers across all units,

Investigation results

Lot Trace

Lot tracing was not possible because the imprinted batch number H6980H05 is not a genuine Roche batch number for Polivy.

Packaging Material Investigation

Roche investigated the provided pictures against a genuine retain sample. The investigation revealed significant differences and clear verification of counterfeiting. Key discrepancies included incorrect artwork (such as incorrect dosages and a fake GTIN), poor overall printing quality, and incorrect box dimensions and perforations. Furthermore, the variable data was entirely incorrect, featuring a fake batch number, a missing 2D-matrix code, and identical fake serial numbers across all four boxes. Finally, the Tamper Evident labels were fake and did not match genuine Roche labels.

Chemical Analysis

Chemical analysis could not be performed since the physical sample was not provided.

Conclusion

Although a complete investigation could not be performed without the physical samples, the packaging material investigation of the provided pictures revealed clear verification for counterfeited packaging material. Roche classifies the displayed material as counterfeits of Polivy and will close Veeva record CMP-006097 as a confirmed counterfeit.

Sincerely,

Signed by:



Signer Name: Thomas Eicher
Signing Reason: I approve this document
Signing Time: 04-Jul-2026 | 5:42:33 PM CEST
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Dr. Thomas Eicher

Global Quality Manager

Signed by:



Signer Name: Gernot Scharf
Signing Reason: I approve this document
Signing Time: 04-Jul-2026 | 3:58:44 PM CEST
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Gernot Scharf

Global Quality Manager