

Islamic Republic of Iran
Iranian Food and Drug Administration
Tehran
Iran

Date: 06 August 2026

Subject: CN-136798 /CN-136898: Notification of suspected counterfeit product (Jakavi 20mg batch A0303H)

Dear Sir/ Madam,

Novartis is a global pharmaceutical company dedicated to the development, manufacturing, and commercialization of innovative medicinal products worldwide.

Novartis takes this opportunity to express its gratitude to the Iranian Food and Drug Administration, for their dedicated efforts in safeguarding and enhancing public health and for ensuring the welfare of the Iranian population through direct oversight, particularly concerning medicinal products.

We would like to inform you that Novartis has recently become aware of two quality concerns from separate complainants in Turkey regarding **the authenticity of Jakavi® (ruxolitinib) 20 mg, batch A0303H ("Product")**.

- (1)** The first complaint was submitted by a relative of a patient in Turkey, who reported that the Product had been purchased from a pharmacy in Iran and requested confirmation of its authenticity.
- (2)** The second complaint was submitted by an individual from turkey similarly requested confirmation of its authenticity.

The photos provided with both complaints show the same batch number (**A0303H**) and include an **Iran Food and Drug Administration (IFDA) authenticity label**.

It is important to note that **Jakavi is neither registered nor commercialized in Iran**.

Furthermore note, that Novartis has appointed distributors, such as Shafayab Gostar (PJS), who are responsible for ensuring that registered and commercialized products released to the market comply with registered specifications, as well as local and international regulatory guidelines. Pharmaceutical products require specific and critical capabilities throughout the supply chain process to guarantee that the medicinal products reaching the patients meet the appropriate requirements. Therefore, Novartis is not able to guarantee that the quality and efficacy of the products meet such required standards, which could lead to potential safety concerns.

Photos of the suspect samples were provided to Novartis by the complainants. A detailed comparison was conducted between these photos of the suspected sample and Novartis retained reference samples. Based on this review, no apparent discrepancies or signs of counterfeiting were identified. However, as the physical sample has not been retrieved, Novartis is not in a position to determine whether the product is authentic or counterfeit.

We are confident that the relevant authorities will take the appropriate measures to continue supporting the local patient.

In case you need any further clarification, please do not hesitate to contact us at hiba.abdelali@novartis.com

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