Safety communication

[15/06/2025]

Risk of Interstitial Lung Disease with BCR-ABL Tyrosine Kinase Inhibitors.

The Saudi Food and Drug Authority (SFDA) would like to remind healthcare professionals about the potential risk of Interstitial Lung Disease (ILD) associated with the use of BCR-ABL tyrosine kinase inhibitors (TKIs), including: Alectinib, brigatinib, crizotinib, dasatinib, imatinib, lapatinib, nilotinib, sunitinib, and vandetanib. ILD is a serious adverse reaction that may occur in patients undergoing treatment with these medications.

Interstitial lung diseases encompass a broad spectrum of conditions, characterized by inflammation or fibrosis of the alveolar wall, leading to impaired gas exchange. Symptoms can include dyspnea, hypoxia, cough, wheezing, chest pain, or interstitial infiltrates seen on chest radiology.

The SFDA observed reports from global health authorities indicating that BCR-ABL TKIs have been associated with cases of ILD, which may manifest as an acute or unexplained worsening of respiratory symptoms. These symptoms can include cough, difficulty breathing, and painful breathing.

Healthcare professionals are advised to be vigilant in identifying any signs of ILD, especially in patients who present with new or worsening respiratory symptoms.

The SFDA advises healthcare professionals to ensure:

1. Closely monitor patients for signs and symptoms of ILD, such as unexplained cough, dyspnea, or hypoxia.
2. Promptly evaluate any patient presenting with respiratory symptoms for ILD and consider discontinuing the use of the TKI if ILD is confirmed.

3. Consider alternative therapies for patients at high risk of ILD or those who have experienced respiratory symptoms while on treatment.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

Website: https://ade.sfda.gov.sa

SFDA RMM Webpage: