



## SFDA SAFETY COMMUNICATION

01/03/2018

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### **Risk of Lower Limb Amputation Associated with the Use of Canagliflozin (Invokana®)**

The Saudi Food and Drug Authority (SFDA) would like to draw Health Care Professionals (HCPs) attention to the risk of increased number of lower limb amputation cases as a consequence of using a pharmaceutical product called canagliflozin (Invokana®). The risk appears to be exacerbated in patients with pre-existing peripheral blood vessels disease in their lower body limbs.

INVOKANA® (canagliflozin) is an oral hypoglycemic medicine that helps to achieve favorable glycemic control. The approved dosage forms for marketing in Saudi Arabia are: INVOKANA® 100 mg and 300 mg film-coated tablet.

Internationally reported cases indicate that there is an increased risk of lower limb amputation (primarily the toe). Such an adverse reaction was observed after canagliflozin intake. However, a data mining job was carried out to search for similar reported cases in Saudi Arabia using the National Pharmacovigilance and Drug Safety Center (NPC) database. The NPC database did not show any locally reported cases addressing canagliflozin and lower limb amputation.

The SFDA recommends that concerned HCPs should monitor all patients for lower limbs problems before INVOKANA® therapy initiation. In addition, HCPs should be vigilant for any lower limb complications that may develop through or after treatment. Patients should be advised to seek for an immediate medical help if they experience symptoms of serious lower limbs problems, such as lower-extremity skin ulcer, infection, osteomyelitis or gangrene.

Meanwhile, the SFDA notified the marketing authorization holder (MAH) to update the summary of product characteristics (SPC) and patient information leaflet (PIL) to address the emerging safety concern to be aligned with the available evidence based information.

**Report Adverse Drug Events (ADEs) to the SFDA.**

The SFDA urges both healthcare professionals and patients to report ADEs raised after using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)

Saudi Food and Drug Authority (SFDA) - Drug sector

3292 Northern Ring Road

Al Nafal District

Riyadh 13312 – 6288

Kingdom of Saudi Arabia

Toll call center: 19999

Tel: 011 2038222 ext. 2317, 2356, 2340, 5372.

Fax: 011 2057662

Email: [NPC.Drug@sfda.gov.sa](mailto:NPC.Drug@sfda.gov.sa)