



P.17011/01/2020-21-PvPI
Indian Pharmacopoeia Commission
National Coordination Centre-Pharmacovigilance Programme of India
(Ministry of Health & Family Welfare, Govt. of India)

Sector-23, Rajnagar,
Ghaziabad-201002, U.P
Dated: March 04, 2021

To,

The Coordinators,
Adverse Drugs Reactions Monitoring Centre (AMC),
Pharmacovigilance Programme of India.

Sub: Sensitization for the monitoring & reporting of Adverse Reactions related to the use of SGLT2 inhibitors - regarding.

Sir/Madam,

The Sodium Glucose Co-transporter-2 (SGLT2) inhibitors are second-line drugs used for the management of Type-II Diabetes mellitus. SGLT2 inhibitors are a new class of Antidiabetic agents; hence the safety profile of these agents is under the constant surveillance of Pharmacovigilance Programme of India.

2. There are safety reports available from other regulatory agencies on the use SGLT2 inhibitors. The following table provides a compilation of ADRs associated with SGLT2 inhibitors:

S. No.	Drug	Adverse Drug Reaction	Regulatory Authority	Source
1.	SGLT2 Inhibitors	Risk of Toe amputation	European Medicines Agency (EMA)	https://www.ema.europa.eu/en/news/splt2-inhibitors-information-potential-risk-toe-amputation-be-included-prescribing-information
			United States Food & Drug Administration (USFDA)	https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-confirms-increased-risk-leg-and-foot-amputations-diabetes-medicine
Diabetic ketoacidosis		Health Canada	https://www.hsa.gov.sg/announcements/safety-alert/interim-update-on-risk-of-serious-ketoacidosis-associated-with-sodium-glucose-cotransporter-2-(splt2)-inhibitors	
Fournier's gangrene		Medical and Healthcare products Regulatory Agency (MHRA, UK)	Medical and Healthcare products Regulatory Agency. SGLT2 inhibitors: reports of Fournier's gangrene. Drug Safety Update 2019;12(7):3	
		United States Food & Drug Administration (USFDA)	https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/sodium-glucose-cotransporter-2-splt2-inhibitors	

3. In view of the above, you are requested to closely monitor the above mentioned Adverse Reactions with the use of SGLT2 inhibitors.

With thanks & regards,


(Dr. Jai Prakash)

Senior Principal Scientific Officer