

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 838
TO BE ANSWERED ON 5TH FEBRUARY, 2021**

ANTI DIABETES MEDICINES

838. SHRI SHANMUGA SUNDARAM K.:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government is aware of the fact that adverse drug reactions are associated with the use of a new class of anti-diabetes medicines (SGLT-2 inhibitors) in India;
- (b) if so, the details thereof and any such adverse reports received from States/UTs particularly Karnataka;
- (c) whether the Drug Controller of India has given permission to market this medicine in India, if so, the details thereof; and
- (d) the steps taken by the Government to create awareness among the millions of diabetic patients in India against the usage of SGLT-2 use?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a): Central Drugs Standard Control Organisation (CDSCO) was notified about a Health Canada communication to all Sodium-Glucose Co-transporter-2 (SGLT2) inhibitor Marketing Authorization Holders regarding a Summary Safety Review (SSR) on the potential risk of pancreas inflammation (acute and chronic).

United States Food & Drug Administration (USFDA) in its Drug Safety Communications (DSC) stated that cases of rare but serious infection of the genitals and area around the genitals have been reported with use of SGLT2 inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. USFDA has revised the labels of SGLT 2 inhibitors to include new warnings about the risk to patients.

The issue has been examined in consultation with Subject Expert Committee (SEC) and information available under the pharmacovigilance programme of India has also been obtained.

Accordingly, CDSCO has requested all State Drug Controllers to direct the manufacturers of SGLT2 inhibitor class drugs such as Canagliflozin, Dapagliflozin, Empagliflozin, etc. under their jurisdiction to include the following warning in the package insert and promotional literature of these drugs:

Warning - Cases of a rare but serious infection of the genitals and area around the genitals have been reported with this class of type 2 diabetes medicines i.e., Sodium-Glucose Co-

transporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene.

(b): The details of adverse effects in respect of SGLT-2 inhibitors reported under the Pharmacovigilance Programme of India (PvPI) from Karnataka are as per **Annexure**.

(c): CDSCO has given permission to import/market formulation of following SGLT-2 inhibitors: Canagliflozin, Dapagliflozin & Empagliflozin including FDC like Canagliflozin + Metformin, Dapagliflozin + Metformin, Empagliflozin + Metformin & Empagliflozin + Linagliptin and manufacture/market of Remogliflozin and Remogliflozin + Metformin.

(d): As stated above, all the State Drug Controllers have been requested to direct the manufacturers of SGLT 2 inhibitor class drugs to include suitable warning in the package insert and promotional literature of these drugs.

Annexure

S.No	SGLT-2 Inhibitors	No. of Reports	Adverse Effects
1	Canagliflozin	3	<ul style="list-style-type: none">• Muscle weakness• Urinary tract infection• Encephalopathy• Sepsis• Diabetic ketoacidosis• Kidney dysfunction
2	Dapagliflozin	6	<ul style="list-style-type: none">• Burning sensation mucosal• Heartburn• Epigastric discomfort• Ketoacidosis• Hypoglycaemia• Glycosuria• Lichen Planus• Urinary tract infection• Genital infection
3	Empagliflozin	7	<ul style="list-style-type: none">• Rash• Itching• Balanitis• Hyperacidity• Laziness• Lethargy• Appetite lost• Somnolence• Retching• Nausea• Urinary tract infection• Hyperkalaemia• Fournier gangrene
4	Remogliflozin	6	<ul style="list-style-type: none">• Hyponatremia• Genital candidiasis• Asymptomatic hypoglycemia• Skin trophic ulcer• Polyuria• Bilateral pneumonia