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

LOK SABHA
UNSTARRED QUESTION NO.4344
TO BE ANSWERED ON 19TH JULY, 2019

ADVERSE DRUG REACTION

4344. SHRI SHANMUGA SUNDARAM K.:
SHRI MAGUNTA SREENIVASULU REDDY:

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

(a) whether the Government is aware about a report on the adverse drug reactions associated with the use of a new class of anti-diabetes medicines (SGLT-2 inhibitors) in India;

(b) if so, the details thereof and the action taken thereon;

(c) whether the Drug Controller of India has given the permission to market this medicine in India and if so, the details thereof;

(d) whether the Ministry is having any details of these medicines being used and its adverse effects reported in Tamil Nadu and if so, the details thereof; and

(e) the steps taken by the Government to create awareness among millions of people in this regard?

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

(a) & (b): Yes. Central Drugs Standard Control Organisation (CDSCO) was notified by the concerned company 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 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 Cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene

(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.

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

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

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Annexure

S.No	SGLT-2 Inhibitors	No. of Reports	Adverse Effects
1	Canagliflozin	3	• Vulval abscess • Weight increased • Ulvovaginal mycotic infection • Hypotension • Thirst
2	Dapagliflozin	9	• Balanoposthitis • Muscular weakness • Haematuria • Weight increased • Pyelonephritis • Urinary tract infection • Ketosis • Dizziness • Glomerular filtration rate decreased • Blood creatinine increased
3	Empagliflozin	6	• Blood creatinine increased • Acute kidney injury • Sepsis • Urinary tract infection • Vaginal discharge • Hypoaesthesia • Chest discomfort