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

LOK SABHA
UNSTARRED QUESTION NO. 1067
TO BE ANSWERED ON 18TH SEPTEMBER, 2020

ANTI-DIABETES MEDICINES

1067. DR. VISHNU PRASAD M.K.:
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 action taken thereon;

(c) whether the Government has received any adverse reports with regard to the use of this medicine particularly in Tamil Nadu; if so, the details thereof;

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

(e) the steps taken by the Government to create awareness among the millions of diabetic patients in India against the usage of SGLT-2 medicine?

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

(a) & (b): 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 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): 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.

(d): 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.

(e): 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.

Annexure

S. No.	SGLT2 Inhibitors	No. of Reports	Adverse Reactions
01	Dapagliflozin	10	• Balanoposthitis • Muscular Weakness • Haematuria • Weight Gain • Pyelonephritis • Urinary Tract Infection • Ketosis • Dizziness • Glomerular Filteration rate decreased • Blood Creatinine increased • Increased Urination
02	Empagliflozin	08	• Urinary Tract Infection • Blood Creatinine increased • Acute Kidney Injury • Sepsis • Numbness • Euglycemic Ketoacedosis • Leucorrhoea • Chest Heaviness • Burning Micturition • Vaginal discharge • Hypoaesthesia
03	Canagliflozin	03	• Vulval abscess • Weight Increased • Ulvovaginal mycotic infection • Hypotension • Thirst
04	Remogliflozin	01	• Cystitis