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

LOK SABHA
UNSTARRED QUESTION NO. 4910
TO BE ANSWERED ON 01st APRIL, 2022

ADVERSE REACTION OF ANTI-DIABETES MEDICINE

4910: SHRI VELUSAMY P.:

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

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

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a): Central Drugs Standard Control Organization (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 was examined in consultation with Subject Expert Committee (SEC) of CDSCO and information available under the Pharmacovigilance Programme of India (PvPI) has also been obtained.

Accordingly, CDSCO has requested all State Drug Controllers to direct the manufacturers of SGLT2 inhibitor class drugs named Canagliflozin, Dapagliflozin, Empagliflozin, 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."

(b): The details of adverse effects (no. of adverse drug reactions reported) in respect of SGLT-2 inhibitors reported under the PvPI from Tamil Nadu are as below**:**
Euglycaemic diabetic ketoacidosis (3), Urinary tract infection (3), Burning micturition (2), Dysuria (2), Serum creatinine increased (2), Genital inflammation (1), Balanitis (1), Genital redness (1), Chest heaviness (1), Cough (1), Cystitis (1), BUN increased (1), Hemoptysis (1), Hypotension (1), Leukorrhoea (1), Numbness of upper arm (1), Pyelonephritis (1), SGPT increased (1), Thirst excessive (1), Vaginal candidiasis (1), Urination frequency (1), Weight increase (1).

(c) & (d): CDSCO has given permission to import/market formulations of following SGLT-2 inhibitors: Canagliflozin, Dapagliflozin & Empagliflozin including Fixed Dose Combinations (FDC) like Dapagliflozin + Metformin HCL, Empagliflozin +Linagliptin, Empagliflozin + Metformin HCL, Canagliflozin + Metformin HCL , Dapagliflozin + Metformin, Remogliflozin Etabonate + Metformin Hydrochloride, Saxagliptin + Dapagliflozin , Remogliflozin Etabonate + Vildagliptin, Remogliflozin Etabonate + Teneligliptin Hydrobromide Hydrate, Remogliflozin Etabonate + Vildagliptin + Metformin Hydrochloride. Further, all the States were requested to direct the manufactures of SGLT 2 inhibitor class drugs to include warning in the package insert and promotional literature of these drugs.

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