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

LOK SABHA
UNSTARRED QUESTION NO. 787
TO BE ANSWERED ON 14TH DECEMBER, 2018

ANTI-DIABETES MEDICINES

787. SHRI P.C. MOHAN:

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 against this;

(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 Karnataka and if so, the details thereof; and

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

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) & (b): Yes. Central Drugs Standard Control Organisation (CDSCO) 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 State Food & Drugs 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 was examining addition of a new warning about the risk to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

The issue was deliberated in the 48th Subject Expert Committee (SEC)'s meeting held on 27.09.2018 in CDSCO.

The committee noted that both the health authorities (Health Canada & USFDA) had not issued any label changes or restriction in SGLT-2 inhibitors. The committee, inter-alia, recommended close monitoring for any new information /development with regard to the use of SGLT-2 inhibitors.

Indian Pharmacopoeia Commission (IPC) through Pharmacovigilance Programme of India (PvPI) keeps watch on pattern of Adverse Drug Reaction (ADR) induced by SGLT-2 inhibitors.

(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.

(d) & (e): The adverse effects in respect of SGLT-2 inhibitors reported under the Pharmacovigilance Programme of India (PvPI) from Karnataka is annexed.

These drugs are marketed in many countries like the USA, Canada, European Union, etc. As opined by the SEC mentioned in part (a) & (b) above, none of the Health Authorities have either banned or issued any label change or advisory against the use of these drugs.

Annexure

S.NO	SGLT-2 Inhibitor	No. of Reports	Adverse Effects
1	Canagliflozin	3	• Renal impairment, Diabetic ketoacidosis, Sepsis, Encephalopathy • Muscular weakness • Urinary tract infection
2	Dapagliflozin	4	• Epigastric discomfort, Dyspepsia, Burning sensation mucosal • Genital infection, Urinary tract infection, Ketoacidosis • Ketoacidosis • Glycosuria
3	Empagliflozin	3	• Balanoposthitis • Urinary tract infection • Urinary tract infection