

# FIRST CASES OF INFECTION FROM DIABETES MEDICATION IN INDIA

Relevant for: Science & Technology | Topic: Biotechnology, Genetics & Health related developments

After the U.S. and Canada, India too has admitted incidence of a rare but serious infection of the genitals and area around the genitals among Type 2 diabetes patients using sodium-glucose cotransporter-2 (SGLT2) inhibitors (a class of Type 2 diabetes medication).

This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene.

As a precautionary measure, the Central Drugs Standard Control Organisation (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 warnings in the package and promotional literature of these drugs.

The Health Ministry, responding to a question on the adverse reaction to the anti-diabetes medicine by P. Velusamy, MP, submitted the information recently.

SGLT2 inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors are recommended as preferred add-on oral anti-diabetic drugs (OADs) after metformin among Type-2 diabetes mellitus (T2DM) patients with atherosclerotic cardiovascular disease (ASCVD), heart failure (HF), and chronic kidney disease (CKD). They are generally many times costlier than other OADs, experts say.

The Ministry submitted in Parliament that CDSCO was notified about a Health Canada communication to all those authorised to market SGLT2 inhibitors regarding a summary safety review (SSR) on the potential risk of pancreas inflammation (acute and chronic).

The United States Food and Drug Administration (USFDA), in its drug safety communications (DSC), has cautioned about cases of rare but serious infection of the genitals and area around the genitals being reported with use of SGLT2 inhibitors.

"This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. The USFDA has revised the labels of SGLT 2 inhibitors to include new warnings about the risk to patients," the Ministry said.

It added that the issue was examined in consultation with the Subject Expert Committee (SEC) of CDSCO and information available under the Pharmacovigilance Programme of India (PvPI) has also been obtained.

Union Health Minister Mansukh Mandaviya had stated in Parliament that the exact number of patients suffering from diabetes in India was not known. However, as per 10th edition of Diabetes Atlas 2021 of International Diabetes Federation (IDF), the estimated number of patients with diabetes between the age group of 20 and 79 is 74.2 million in year 2021 and it is estimated to be increased to 124.8 million in year 2045.

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