

File No.12-01/16-DC (pt-110)
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan,
Kotla Road, New Delhi
Dated: 02-03-2016

To
All State Drugs Controllers

Subject: Updated package insert (PI) for Empagliflozin tablets 10mg and 25mg based on Company Core Data Sheet (CCDS) dated 10 Jul 2015 and 07 Jan 2016 - regarding.

Sir,

CDSCO has approved the drug Empagliflozin 10mg and 25mg film coated tablets for the indication of "As an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus" on 7th May 2015.

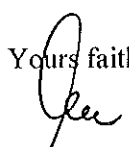
Subsequent to this, U.S. Food and Drug Administration (US FDA) had issued warning on 15th May 2015, via Drug Safety Communication that sodium-glucose cotransporter-2 (SGLT2) inhibitors prescribed in type-2 diabetes (Viz., Canagliflozin, Dapagliflozin and Empagliflozin) may lead to ketoacidosis, a serious condition where the body produces high levels of blood acids called ketones that may require hospitalization. US FDA had revised the Drug Safety Communication dated 4th December 2015 after safety review which resulted in added warnings about the risks of too much acid in the blood and of serious urinary tract infections. Both conditions can result in hospitalization.

Accordingly, the firm M/s. Boehringer Ingelheim has revised the package insert at United States for Empagliflozin dated March 2016 incorporating the label of 'Special warnings and Precautions' with Diabetic ketoacidosis and urinary tract infection (e.g. pyelonephritis and urosepsis) and "Side effect" with pruritis, volume depletion and dysuria, derived from post-marketing experience.

This office has issued permission for updating the package insert with above information in accordance with the international package insert.

This is for your information and necessary action taken in the matter may please be communicated to the undersigned.

Yours faithfully,


(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:-

- 1) All Zonal/Sub Zonal offices of CDSCO
- 2) Diabetic Association of India
- 3) India Drug Manufacturers Association (IDMA)