

ಕರ್ನಾಟಕ ವಿಧಾನ ಪರಿಷತ್ತು

ಚುಕ್ಕೆ ಗುರುತಿಲ್ಲದ ಪ್ರಶ್ನೆ ಸಂಖ್ಯೆ	1110
ಸದಸ್ಯರ ಹೆಸರು	ಶ್ರೀ ಎಂ. ನಾಗರಾಜು (ವಿಧಾನ ಸಭೆಯಿಂದ ಚುನಾಯಿತರಾದವರು)
ಉತ್ತರಿಸಬೇಕಾದ ದಿನಾಂಕ	17-03-2025
ಉತ್ತರಿಸುವ ಸಚಿವರು	ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಚಿವರು

ಕ್ರ. ಸಂ.	ಪ್ರಶ್ನೆ	ಉತ್ತರ
ಅ)	ರಾಜ್ಯದಲ್ಲಿ ಹೊಸ ವರ್ಗದ ಮಧುಮೇಹ ವಿರೋಧಿ ಔಷಧಿಗಳಾದ SGLT-2 ಬಳಕೆಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಆಗುವ ದುಷ್ಪರಿಣಾಮಗಳ ಕುರಿತು ಸರ್ಕಾರದ ಗಮನಕ್ಕೆ ಬಂದಿದೆಯೇ?	ಸದರಿ ವರ್ಗದ ಔಷಧಿಗಳಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಹೊರ ದೇಶಗಳಾದ ಕೆನಡ ಮತ್ತು ಅಮೆರಿಕಾದಲ್ಲಿ ಅಡ್ಡ ಪರಿಣಾಮ ಬೀರಿರುವ ಬಗ್ಗೆ ವರದಿಯಾಗಿರುವ ಮೇರೆಗೆ ಕೇಂದ್ರ ಸರ್ಕಾರದ Central Drugs Standard Control Organization (CDSCO), New Delhi ಸಂಸ್ಥೆಯವರು ಈ ಅಡ್ಡ ಪರಿಣಾಮ ಬೀರುವ ಔಷಧಿಗಳ ಬಗ್ಗೆ ಗಮನಿಸಿ, ಎಲ್ಲಾ ರಾಜ್ಯಗಳಿಗೆ ದಿನಾಂಕ:25.03.2019ರಂದು ಸುತ್ತೋಲೆ ಹೊರಡಿಸಿ Product Literature/ Product Inserts ಗಳಲ್ಲಿ ಸದರಿ ಅಡ್ಡ ಪರಿಣಾಮದ ಬಗ್ಗೆ ಎಚ್ಚರಿಕೆಯನ್ನು ನೀಡಲು ನಿರ್ದೇಶಿಸಿರುತ್ತಾರೆ (ದಿನಾಂಕ:25.03.2019ರ ಸುತ್ತೋಲೆಯ ಪ್ರತಿಯನ್ನು ಲಗತ್ತಿಸಿದೆ).
ಆ)	ರಾಜ್ಯದಲ್ಲಿ ಮೇಲಿನ ಔಷಧಿಗಳ ದುಷ್ಪರಿಣಾಮಗಳ ವರದಿಯನ್ನು ಸರ್ಕಾರ ಸ್ವೀಕರಿಸಿದೆಯೇ? ಇದ್ದಲ್ಲಿ ಅದರ ವಿವರಗಳೇನು?	ಸದರಿ ಸುತ್ತೋಲೆಯ ಮೇರೆಗೆ ಆಹಾರ ಸುರಕ್ಷತೆ ಮತ್ತು ಔಷಧಿ ಆಡಳಿತ ಇಲಾಖೆಯಿಂದ ದಿನಾಂಕ:01.04.2019ರಂದು ಸದರಿ ವಿಷಯದ ಬಗ್ಗೆ ತಯಾರಿಕೆ ಸಂಸ್ಥೆಗಳಿಗೆ ಮಾಹಿತಿಯನ್ನು ನೀಡಿ, ಸುತ್ತೋಲೆಯಲ್ಲಿ ನೀಡಿರುವ ಎಚ್ಚರಿಕೆಗಳನ್ನು ಅನುಷ್ಠಾನಗೊಳಿಸಲು ನಿರ್ದೇಶನ ನೀಡಲಾಗಿದೆ (ದಿನಾಂಕ:01.04.2019ರಂದು ಇಲಾಖೆಯಿಂದ ಹೊರಡಿಸಿದ ಸುತ್ತೋಲೆಯ ಪ್ರತಿಯನ್ನು ಅನುಬಂಧದಲ್ಲಿ ಲಗತ್ತಿಸಿದೆ).
ಇ)	ಕರ್ನಾಟಕದ ಔಷಧ ನಿಯಂತ್ರಣ ಇಲಾಖೆಯು ಮಧುಮೇಹ ರೋಗಿಗಳ ಮೇಲೆ ಈ ಔಷಧಿಯ ದುಷ್ಪರಿಣಾಮಗಳ ಕುರಿತು ತನ್ನ ವರದಿಯನ್ನು ಸಲ್ಲಿಸಿದೆಯೇ? ಇದ್ದಲ್ಲಿ ವರದಿಯ ಪ್ರತಿಯನ್ನು ನೀಡುವುದು.	ಸದರಿ ಔಷಧದ ಬಗ್ಗೆ ಈ ಇಲಾಖೆಯಲ್ಲಿ ಯಾವುದೇ ಅಡ್ಡ ಪರಿಣಾಮ ಬೀರಿರುವ ಬಗ್ಗೆ ದೂರುಗಳು ಸ್ವೀಕೃತವಾಗಿರುವುದಿಲ್ಲ.
ಈ)	ಕರ್ನಾಟಕದಲ್ಲಿ ಲಕ್ಷಾಂತರ ಮಧುಮೇಹ ರೋಗಿಗಳಲ್ಲಿ SGLT-2 ಬಳಕೆಯ ವಿರುದ್ಧ ಜಾಗೃತಿ ಮೂಡಿಸಲು ಸರ್ಕಾರ ಕೈಗೊಂಡಿರುವ ಕ್ರಮಗಳೇನು?	

ಕಡತ ಸಂಖ್ಯೆ: ಆಕುಕ 73 ಪಿಟಿಡಿ 2025

(ದಿನೇಶ್ ಗುಂಡೂರಾವ್)
ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಚಿವರು

**GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT**

No. DCD/MFG/CR-MISC-131/18-19

Office of the Drugs Controller
for the State of Karnataka
Palace Road, Bengaluru 01.

Date: **01 APR 2019**

CIRCULAR

Sub: Drugs & Cosmetics Act, 1940 and Rules 1945 – Safety Warning for
SGLT2 inhibitors - reg.

Ref: Drugs Controller General (India) letter No. F.No. 12-74/13-DC.
dated 25.03.2019.

With reference to the above, I am directed to enclose copy of the letter cited under
above reference for information and necessary action.

Yours faithfully,
for **DRUGS CONTROLLER**




(P. RAMESH)

DEPUTY DRUGS CONTROLLER (I/c)

To,

All Enforcement Officers.

F. No. 12-74/13-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road
New Delhi

Dated: 25-03-2019

To
All State/UT Drugs Controllers,

Subject: - Safety Warning for SGLT2 inhibitors - regarding

Sir,

Sodium-Glucose Cotransporter-2 (SGLT2) inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine. SGLT2 inhibitor class includes drugs such as Canagliflozin, Dapagliflozin, Empagliflozin etc.

This office has received safety updates of the said drugs along with safety communications by Health Canada and US-FDA from M/s Johnson & Johnson Private Limited and M/s Boehringer Ingelheim India Pvt. Ltd.

Health Canada has published Summary Safety Review of SGLT2 inhibitors by assessing the potential risk of inflammation of the pancreas (acute and chronic pancreatitis) on 20.07.2018 wherein it has been concluded that there may be a link between the use of SGLT2 inhibitors and acute pancreatitis. Health Canada is working with the manufacturers to update the product safety information on SGLT2 inhibitors to inform about this risk and will continue to monitor safety information involving SGLT2 inhibitors to identify and assess potential harms.

USFDA has given safety announcement on 29.08.2018 wherein the U.S. Food and Drug Administration (FDA) is warning that 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 penneum, is also referred to as Fournier's gangrene. They require a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient.

In light of concerns raised with regard to safety of SGLT2 inhibitors, the matter has been examined by CDSCO in consultation with the Subject Expert Committee (SEC-Endocrinology & Metabolism) in its meeting held on 27.09.2018 wherein presentation was made by the firm before the committee about the safety signals from Health Canada regarding Pancreatitis and from USFDA regarding Fournier's gangrene with the use of SGLT-2 inhibitors.

On the basis of these reports the SEC had recommended that

- 1) Data should be obtained from NCC-PvPI regarding any signals on the SGLT2 inhibitors emphasizing the above two conditions in Indian patients.
- 2) CDSCO should closely monitor for any further new information /development with SGLT2 inhibitors.

In view of the above, IPC, NCC-PvPI was requested to provide the information about the details ADRs, if any or any signals on SGLT-2 inhibitors emphasizing the acute pancreatitis & Fournier's gangrene in Indian patients received under PvPI. Accordingly, PvPI has replied with the details of Individual Case Safety Reports (ICSRs) reported to them.

The issue along with ICSRs received from PvPI was deliberated again in the SEC meeting held on 22.01.2019.

The committee took cognizance of ICSRs received from IPC, NCC-PvPI & deliberated on the issue in light of global reporting on the subject.

After detailed deliberation, the committee has opined that NCC PvPI should be requested to furnish further details on 08 ICSRs reported for genital infections with the use of SGLT2 inhibitors in terms of severity, type, duration & outcome of these infections. In the mean time the committee has recommended that CDSCO should request all the State Drugs Controllers to direct the manufacturers of SGLT2 inhibitors to include warning in this regard in the package insert as taken by other regulatory authorities like USFDA.

Accordingly, you are requested to direct the manufacturers of SGLT2 inhibitor class drugs such as Canagliflozin, Dapagliflozin, Empagliflozin, etc. under your 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.

Action taken in this regard may be intimated to this office.

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy for information and necessary follow up to:

- All Zonal/Sub Zonal offices of CDSCO.