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

LOK SABHA
UNSTARRED QUESTION NO. 3307
TO BE ANSWERED ON 13TH MARCH, 2020

BANNING CHEAP ANTI-DIABETIC DRUG

3307. SHRI SHANMUGA SUNDARAM K.:

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

(a) whether the Government has banned the anti-diabetic drug Pioglitazone which is cheaper and is widely used by the poor and middle class patients in the country;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Government has undertaken any scientific study to ascertain the risk of bladder cancer caused by Pioglitazone, if so, the details thereof and if not, the reasons therefor;

(d) whether the Government has received any specific complaint from any research organizations or reputed hospitals, if so, the details thereof and action taken thereon; and

(e) whether the Government is having any detailed report of the adverse effects of this drug from FDA (Federal Drug Administration) of USA, if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) & (b): In light of reported risk of bladder cancer associated with the use of pioglitazone and restriction imposed on marketing of pioglitazone by other countries, the manufacture for sale, sale and distribution of the drug Pioglitazone and formulations containing Pioglitazone for human was suspended vide gazette notification GSR 379 (E) dated 18.06.2013.

Subsequently, the Drugs Technical Advisory Board (DTAB) recommended for revocation of the said suspension subject to some conditions. After examination, the Government vide gazette notification GSR No. 520 (E) dated 31.07.2013 revoked the suspension of the manufacturing and sale of the drug subject to the condition that the manufacturer shall mention the following on their package insert and promotional literature of the drug:-

a) The drug should not be used as first line of therapy for diabetes.

b) The manufacturer should clearly mention following box warning in bold red.

“Advice for healthcare professionals:

- Patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone.
- Prescribers should review the safety and efficacy of pioglitazone in individuals after 3–6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (e.g., reduction in glycosylated haemoglobin, HbA1c).
- Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age, current or past history of smoking, exposure to some occupational or chemotherapy agents such as cyclophosphamide, or previous irradiation of the pelvic region.
- Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone.”

(c): No such study was undertaken by the Central Drugs Standard Control Organisation (CDSCO) and the recommendation for suspension, as mentioned above, was based on reported risks and restriction imposed by other countries.

(d): A complaint was received from one of the Diabetic Care Centres. The complaint was examined and replied accordingly.

(e): As per the safety announcement dated 12.12.2016 by the Food & Drug Administration of the United States of America available on their website, pioglitazone may be associated with an increased risk in urinary bladder cancer. However, the drug is marketed in USA with warning about the risk.

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