

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:1784

ANSWERED ON:16.08.2013

BAN ON ANTI DIABETIC DRUG

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

- (a) whether Pioglitazone, an oral antidiabetic drug is banned in the country;
- (b) if so, the reasons therefor;
- (c) whether the Drugs Technical Advisory Board has recommended to revoke the ban on the said drug and to allow to its sale with a boxed warning.
- (d) if so, whether the Government has conducted any study to ensure the safety of the drug; and
- (e) if so, the details and the outcome thereof and the time by which a final decision is likely to be taken by the Government in the matter?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) to (e): The Government had suspended the manufacture for sale, sale and distribution of the drug Pioglitazone and formulations containing Pioglitazone for human use vide Gazette Notification GSR 379 (E) dated 18-06-2013 as certain reports, published in medical journals raised the issue of safety concerns on continued use of the drug. However, the Drugs Technical Advisory Board (DTAB) recommended for revocation of the suspension of the manufacture and sale of the drug on the opinion of an Expert Committee constituted for the purpose. It also recommended that the drug should however be allowed to be marketed with a box warning and should also be put under focus Pharmacovigilance Programme. Accordingly, the Government issued a Gazette Notification GSR 520 (E) dated 31-07-2013 revoking the suspension of the manufacturing and sale of the drug subject to the following condition that the manufacture shall mention on their package insert and promotional literature of the drug:

1. The drug should not be used as first line of therapy for diabetes.
2. The manufacturer should clearly mention following box warning in bold red letters:- "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 (eg. 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".