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

LOK SABHA
UNSTARRED QUESTION NO. 1489
TO BE ANSWERED ON 4TH MARCH, 2016

BANNED MEDICINE

1489. SHRIMATI BHAVANA PUNDALIKRAO GAWALI PATIL:
SHRI KRUPAL BALAJI TUMANE:

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

(a) whether many medicines which are banned in developed countries are freely sold in India;

(b) if so, the details of such medicines which are banned in foreign countries and freely available in India; and

(c) the steps taken/being taken by the Government to strictly implement to ban such medicines along with the outcome thereof?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (c): A drug banned / restricted in one country may continue to be marketed in other countries as the respective Governments examine the usage, doses, indications permitted, etc. along with the overall risk-benefit ratio and take decisions on the continued marketing of any drug in that country. In India, safety issues concerning drug formulations are, as and when noted, assessed in consultation with the Expert Committees / Drugs Technical Advisory Board (DTAB). Based on the recommendations of the Expert Committees / DTAB, the Central Government prohibits manufacture, sale and distribution of such drugs in the country. So far, the Central Government has prohibited the manufacture, sale and distribution of 94 drugs. Safety and efficacy issues relating to certain drugs which have been banned in some countries have been examined in consultation with the DTAB/Experts. Some of these have been allowed for continued marketing subject to stipulated condition/restrictions. These include :

(i) Nimesulide:- The manufacture, sale and distribution of Nimesulide formulation for human use in children below 12 years of age has been prohibited in the country.

(ii) Analgin:- The manufacture for sale, sale and distribution of Analgin and its formulations containing Analgin for human use was initially suspended in the country w.e.f. 18.06.2013. Subsequently, DTAB examined the issue of suspension of manufacture and sale of the said drug on 25.11.2013 in its 65th meeting and on the basis of the recommendations of the DTAB, the ban was revoked subject to the condition that manufacturers will be required to mention the following on their package insert and promotional literature of the drug:-

"The drug is indicated for severe pain and pain due to tumour and also for bringing down temperature in refractory cases when other antipyretics fail to do so".

(iii) Pioglitazone:- The manufacture for sale, sale and distribution of the drug Pioglitazone and formulations containing Pioglitazone for human was initially suspended w.e.f. 18.06.2013. Subsequently, DTAB, after examination, recommended for revocation of the suspension of the manufacture and sale of the drug subject to certain conditions and accordingly, the suspension was revoked subject to the condition that the manufacturer shall mention on the package insert and promotional literature of the drug the following:-

a) The drug should not be used as first line of therapy for diabetes.
b) The manufacturer should clearly mention the following box warning in bold red.

"Advice for healthcare professionals:

I. Patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone.
II. 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).
III. 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.

IV. 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."

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