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

LOK SABHA
UNSTARRED QUESTION NO. 1777
TO BE ANSWERED ON 25TH NOVEMBER, 2016

IMPACT OF DRUGS

1777. DR. PRABHAS KUMAR SINGH:

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

(a) whether the Government has undertaken any study to assess the impact of drugs/pharmaceuticals used in the country that are banned in other countries;

(b) if so, the name and number of drugs banned since 2014;

(c) if not, the reasons therefor; and

(d) the other measures taken by the Government to ban of such drugs in the country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)

(a) to (d): 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 experts. Safety and efficacy issues relating to certain drugs which have been banned in some countries have been examined and 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 Subsequently, the ban was revoked subject to the condition that manufacturers will be required to mention the following on their package insert and promotional literature of the drug:-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 use was initially suspended w.e.f. 18.06.2013. Subsequently, the suspension was revoked subject to the condition that the manufacturer shall mention on the package insert and promotional literature of the drug the following:-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.

c) 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).

d) 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.

e) 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."