GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2004
ANSWERED ON:31.07.2015
Banned/Discontinued Drugs
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

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

(a) whether the Government has suspended the manufacture, sale and distribution of certain drugs including antidiabetic drug pioglitazone in the country;

(b) if so, the details of the drugs suspended and the reasons for their suspension during the last three years and the current year;

(c) whether the Government has recently permitted launch of certain antidiabetic drugs against which warning has been issued by the U.S. Food and Drug Administration, if so, the details thereof and the reasons therefor;

(d) whether a study/research has found instances of prescription of medicines to patients suffering from Brain Stroke and Brain Haemorrhage at All India Institute of Medical Sciences, New Delhi which were discontinued in the developed countries due to their non-conformity and if so, the facts in this regard; and

(e) the measures being taken by the Government to keep continuous vigilance on the drugs causing health risks and to update the doctors/masses about the banned/discontinued drugs in the country?

Answer

(a) & (b): Keeping in view the likely risk to human beings and availability of safer alternatives in the country, the following drugs have been banned/suspended during last three years and the current year:
1. Serodiagnostic test kits for diagnosis of tuberculosis on 7th June, 2012.
2. Dextropropoxyphene and formulations containing Dextropropoxyphene for human on 23rd May, 2013.
3. Suspension of fixed dose combination of Flupenthixol + Melitracen on 18th June, 2013. It was subsequently prohibited on 11th July, 2014.
4 . Manufacture and sale of two drugs i.e. Pioglitazone and Analgin were initially suspended in the country on 18th June, 2013. However, based on evaluation of overall safety and efficacy profile, these drugs were subsequently allowed to be marketed in the country with certain restrictions.
(c): Based on pre-clinical and clinical data of safety and efficacy of the drugs, regulatory status in other countries, etc. and recommendation of Subject Expert Committee (SEC), the import and marketing of three anti-diabetic drugs, namely,Canagliflozin, Dapagliflozin and Empagliflozin was approved on 17.11.2014, 25.02.2015 and 07.05.2015, respectively. United States Food and Drug Administration(USFDA)has issued warning on 15.5.2015 for medical professionals and patients that type-2 diabetes medicines- Canagliflozin, Dapagliflozin and Empagliflozin may lead to ketoacidosis, a condition where the body produces high levels of Ketones that may require hospitalization. USFDAis investigating this safety issue and will determine whether changes are needed in the prescribing information for this class of drugs. Subsequently, comments have been sought from the firms permitted to import the drugsabout the warning issued by USFDA.
(d): All India Institute of Medical Sciences, New Delhi has informed that it prescribes only approved medicines to patients.
(e): Safety issues concerning drug formulations, as and when reported, are assessed in consultation with the Expert Committees/Drugs Technical Advisory Board (DTAB). Based on the recommendations of the Expert Committees/DTAB, the Government regulates, restricts or prohibits manufacture, sale and distribution of such drugs in the country.