GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2580
ANSWERED ON:12.03.2010
BANNED DRUGS
Bapurao Shri Khatgaonkar Patil Bhaskarrao;Gaikwad Shri Eknath Mahadeo;Jaiswal Shri Gorakh Prasad ;Laguri Shri Yashbant Narayan Singh;Owaisi Shri Asaduddin;Ram Shri Purnmasi;Reddy Shri Anantha Venkatarami;Siricilla Shri Rajaiah;Yaskhi Shri Madhu Goud

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

(a) whether many blacklisted or banned drugs are being marketed in the country with new names;

(b) if so, the details of such drugs detected and the action taken by the Government thereon;

(c) whether reports have been received by the Government on the adverse effect of diabetic drug Rosiglitazone/Avandia which is banned in many countries;

(d) if so, the details thereof; and

(e) the corrective steps taken or proposed to be taken by the Government to ban the marketing of such drugs in the country?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) & (b): There is no such term - 'blacklisted' in the Drugs and Cosmetics Act and Rules thereunder. However drugs which are prohibited to manufacture and market under Section 26A of Drugs and Cosmetics Act are not permitted to be marketed in the country under any name. Central Drugs Standard Control Organisation (CDSCO) has not received any such information.

(c) to (e): Earlier in 2007, there were reports of increased risk of heart attack with rosiglitazone. In India, the matter was examined by National Pharmacovigilance Advisory Committee (NPAC) in January, 2008 which recommended incorporation of "Box warning" in the package inserted and other promotional literature of formulations containing rosiglitazone. Accordingly all State Drug Controllers were requested to direct manufacturers of rosiglitazone formulation to incorporate the box warning about cardiac risk. In January, 2010 it was reported that one US FDA report concluded that rosiglitazone should be removed from the market.

The safety issues of continued marketing of such drug formulations which have been withdrawn/restricted in some other countries are examined in the conterxt of current knowledge by the Drug Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act.