GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4088
ANSWERED ON:20.03.2015
ACTION AGAINST DRUG MANUFACTURERS
Joshi Shri Pralhad Venkatesh;Kodikunnil Shri Suresh;Muddahanumegowda Shri S.P.;Patole Shri Nanabhau Falgunrao;Raju Shri Gokaraju Ganga;Rao (Avnthi) Shri Muthamsetti Srinivasa;Thota Shri Narasimham

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

(a) whether side-effects of certain drugs including anti-diabetic drug Metformin have been reported in the country, if so, the details thereof and the action being taken by the Government thereon;

(b) whether American and European drug regulators have raised concerns about the testing and manufacturing facilities of certain drug companies including Lupin Ltd. and GVK Bio-sciences manufacturing drugs in the country;

(c) if so, the details of the concerns raised by them and the action being taken by the Government to address the same;

(d) the action taken/proposed to be taken by the Government against the manu- facturers of crocin and paracetamol for allegedly fixing fake labels on these tablets;

(e) whether the Government has received any proposal to introduce certain anti-tuberculosis drugs including Bedaquiline in the country, if so, the details thereof and the action taken/proposed to be taken by the Government thereon; and

(f) the measures being taken by the Government to curb aggressive and unethical promotion of drugs by pharmaceutical companies in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIJAGAT PRAKASH NADDA)

(a): Yes. Adverse drug reactions in the country are monitored under the Phannacovigilance Programme of India. It needs to be recognized that no drugs can be 100% safe and all of them will have some adverse drug reactions. The drugs are, therefore, allowed after taking into account their risk versus benefit profile. From 15th April, 2011 to 28th February, 2015, 1036 adverse drug reactions have been reported in respect of Metformin.

(b) & (c):
I. Isolated cases where concerns have been expressed by regulators of other countries about certain aspects of Indian Pharmaceutical companies exporting drugs to such countries have been reported in the media and on the websites of the regulatory authorities of those countries.

II. The inspectors of Regulatory Authority of France inspected the Bio-availability/ Bio- equivalence study centre of M/s GVK Biosciences Pvt. Ltd. and raised concerns about the "check out ECG" for study volunteers and made a closing remark that GVK Biosciences had replaced ECGs of volunteer by using ECGs taken from other volunteers. It has, however, been noted that the Committee set up by the Drug Controller General (India) has concluded that the studies did not affect, in any way, the safety and well beings of the subjects nor did they affect the determination of bioequivalence which was the main objective of the studies.

III. In January, 2015, the USFDA inspected M/s Lupin's, Pithampur plant and observed non-compliance`s with some parameters of Good Manufacturing Practices. In this context, it needs to be noted that for export of Drugs, the manufacturers/exporters are required to meet the requirement of the importing country which are, on many occasions, over and above the requirements prescribed under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. There is no provision in the Act to ensure compliance with the requirements of the importing country by the manufacturer/exporter.

(d): Central Drugs Standard Control Organization does not have any information regarding alleged fake labels. The State Licensing Authorities are authorized and take action against the manufacturers for non-conformance with the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

(e): Permission to import Bedaquiline uncoated tablets 100 mg has been issued on 14.01.2015 with the condition that it will be used under the Revised National Tuberculosis Control Program (RNTCP) for treatment of multiple drug resistant (MDR) TB patients only.

(f): Adequate provisions exist in the Drugs & Cosmetics Act, 1940 and Rules made thereunder for taking appropriate action against pharmaceutical companies involved in unethical promotion of drugs.