GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1934
ANSWERED ON:31.07.2015
Drug Regulation
Adsul Shri Anandrao ;Parthipan Shri R.;Patil Shri Shivaji Adhalrao;Shrirang Shri Chandu Barne;Sreeramulu Shri B.;Yadav Shri Dharmendra

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 as per some reports/estimates, majority of spurious/substandard/counterfeit drugs sold globally originates from India, if so, the details thereof and the response of the Government
thereto;

(b)whether certain overseas drug regulatory authorities have raised concerns regarding quality and compliance of good manufacturing practices by the Indian drug manufacturers, if so, the details thereof along with the corrective measures being taken by the Government in this regard;

(c) whether the Government proposes to throw open the database on domestic pharmaceutical manufacturers to global stakeholders, if so, the details thereof along with the extent to which it is likely to address the aforesaid issues/concerns;

(d) whether the Government proposes to become a part of a multinational regulatory regime i.e. Pharmaceutical Inspection Cooperation Scheme (PICS) under which India will be obliged to adopt global standards on drug inspections and manufacturing; and

(e) if so, the details thereof along with the steps being taken by the Government for skill development and standardization of the domestic pharmaceutical sector, particularly small/medium sized drug companies

Answer

(a): The Government's attention has been drawn to a working Paper Series entitled "Poor Quality Drugs and Global Trade A Pilot Study" by Roger Bate and others of the National Bureau of Economic Research, published in September, 2014 which reported that India is supplying substandard medicines for markets with non-existent, under-developed or emerging regulatory oversight, notably Africa. The study is misleading. The extent of actual spurious/adulterated drugs is 0.27, 0.11, 0.16 and 0.11 percent for 2011-12, 2012-13, 2013-14 and 2014-15 respectively.
(b): Isolated reports of export of sub-standard quality of drugs by some Indian pharmaceutical companies have appeared in the media and on the websites of the regulatory authorities of foreign countries, etc. from time to time. As per the recent media reports, major regulatory actions taken against Indian Pharmaceutical Companies are as under:

(i.) M/s. Aarti Drugs, Palghar, Tarapur, Maharashtra by United States Food and Drugs Administration (USFDA).
(ii.) M/s IPCA Laboratories plants situated at Pithampur , Indore, M.P. & Piparia in Silvassa by USFDA.
(iii.) M/s Suchem Laboratories, Ahmedabad by USFDA.
(iv.) M/s Emcure Pharmaceutical, Hinjawadi by USFDA.

For export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country.

(c): The Government does not have any proposal to disclose data in addition to what is already placed on the website of the Central Drugs Standard Control Organization.

(d): The Department of Commerce has conducted a study on Pharmaceuticals Inspection Cooperation Scheme (PICS). However, no decision has been taken by the Government to join PICS.

(e): Does not arise.