GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2283
ANSWERED ON:12.08.2011
SPURIOUS AND SUBSTANDARD DRUGS
Anuragi Shri Ghansyam ;Badal Harsimrat Kaur;Dashmunsi Deepa ;Dhotre Shri Sanjay Shamrao;Dutt Smt. Priya Sunil;Kishor Shri Kamal ;Kumar Shri Kaushalendra;Mahto Shri Baidyanath Prasad;Nagar Shri Surendra Singh;Premdas Shri ;Ramasubbu Shri S.;Rana Shri Kadir;Sayeed Muhammed Hamdulla A. B. ;Singh Baba Shri K.C.;Singh Dr. Raghuvansh Prasad;Thakor Shri Jagdish;Veljibhai Jat Poonamben;Viswanathan Shri P.;Wankhede Shri Subhash Bapurao

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

(a) whether the Government has taken note of the various reports in the foreign media which declare India as the largest producer of spurious and substandard drugs and vaccines;

(b) if so, the facts in this regard;

(c) the steps so far taken by the Government to tackle the rising menace of spurious drugs and vaccines indicating the number of raids conducted alongwith the number of such cases detected during each of the last three years and the current year so far, State/UT-wise;

(d) whether the Government has recently constituted a Committee to tackle the problem of spurious drugs and vaccines in the country; and

(e) if so, the details of the recommendations made by the said Committee alongwith the follow up action taken/proposed by the Government thereon?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): The reports in the foreign media are not based on actual survey. The organisation for economic corporation and development in its report published in 2010 had mentioned about the import of fake drugs from India in the European Union. The statistics mentions in the report were related to case of violation of Intellectual Properties Rights recorded in 2005 with TAXUD (European Community's Taxation and Custom Union). Such cases are considered as counterfeit medicines by European Union. The India Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 made thereunder do not, however, recognize linking of the licensing of any drug with its patent status. Nevertheless, the Government has taken up the matter with World Health Organisation as well as other international forums that patent issues should not be confused with the quality of medicines or spurious drugs.

(c): The Government has taken following steps to check the problem of spurious drugs in the country:

(i) The Drugs and Cosmetics Act, 1940 has been amended in 2008 to provide for more stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have been made cognizable and non-bailable.

(ii) Whistle Blower Scheme has been announced to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers are suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

(iii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics Act have been forwarded to the State Drugs Controllers for implementation.

(iv) The inspectorate staff have been instructed to keep vigil and draw samples of drugs for testing/analysis to monitor the quality of drugs moving in the country.

(v) Steps have been taken to strengthen infrastructure, including the manpower of CDSCO for better enforcement. Similarly, State Governments have been requested to augment manpower and infrastructure.

A Statement containing three years data of the number of cases of spurious drugs, prosecutions launched and number of raids is annexed. Data for the current year has not yet been compiled.

(d) No.

(e): Does not arise.