

**GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA**

UNSTARRED QUESTION NO:2847

ANSWERED ON:13.03.2015

BAN ON SUPPLY OF DRUGS BY FOREIGN COUNTRIES

Devi Smt. Rama

Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

- (a) whether Sri Lanka has recently put a ban on supply of drugs by six Indian drugs manufacturing companies due to their poor quality;
- (b) if so, the details thereof;
- (c) the number of such cases in respect of drugs exporting Indian companies falling under regulatory scanner of other countries during the last three years and the current year country-wise; and
- (d) the corrective steps taken/proposed to be taken by the Government to resolve these issues?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (INDEPENDENT CHARGE) (SMT. NIRMALA SITHARAMAN)

(a)& (b) : No report about ban on supply of drugs by Indian pharma companies by Sri Lanka Govt. has come to the notice of Department of Commerce.

(c) : Isolated cases of foreign countries taking action against Indian Pharmaceutical companies involved in export of drugs have been reported from time to time in media, websites of the regulatory authorities of those countries etc. In some cases the major regulatory actions have been taken by some foreign countries. The number of such cases as available with Central Drugs Standard Control Organisation (CDSCO) in the last three years and current year are as under:

S.No. Year No. of cases Name of the country

- 1. 2012 Nil
- 2. 2013 12 USA
- 3. 2014 6 USA
- 4. 2015 Nil

(d) :As per CDSCO, for export of drugs, Indian pharmaceutical companies are required to comply with the regulatory provisions of the importing country. There are no provisions under the Drugs and Cosmetics rules, 1945 which requires CDSCO to ensure the said compliance by the Indian Pharmaceutical companies. Hence CDSCO has no information with respect to corrective steps for resolving these issues. However, respective countries accord their own approvals after inspecting plants located in India.