

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

STARRED QUESTION NO:82

ANSWERED ON:28.11.2014

ANTIBIOTIC DRUGS

Chandumajra Shri Prem Singh;Khadse Smt. Raksha Nikhil

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

- (a) The total quantity and value of antibiotic drugs permitted to be imported from China and other countries during each of the last three years and the current year;
- (b) The mechanism put in place by the Government to ensure the quality of imported antibiotic drugs, predominantly used for further formulations in the country;
- (c) Whether the Government has taken note of the rising number of cases of multidrug resistance due to widespread and indiscriminate use of antimicrobial/antibiotic drugs in the country and if so, the details thereof along with the corrective measures being taken in this regard;
- (d) Whether any study has been conducted in this regard and if so, the details along with the outcome thereof; and
- (e) Whether the Indian Medical Association has urged the medical fraternity to avoid unnecessary prescriptions of antibiotics to patients having viral infections and launched a nation-wide awareness programme in this regard and if so, the details thereof?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 82 FOR 28th NOVEMBER, 2014

(a): The total quantity and value of antibiotic drugs imported from China and other countries for each of last three years and current year is as under:

Bulk Drug (Antibiotic) imported from China					Bulk Drug (Antibiotic) imported from countries other than China				
2011	2012	2013	2014#		2011	2012	2013	2014#	
Qty in	50,18,900	65,44,210	49,86,145		1,20,63,218	7,84,278	10,10,2278	39,015	9,91,871
kgs									
Value	356.27	428.31	367.62		426.68	97.12	123.62	101.30	167.70
(Rs in									
Creore)									

Finished formulation (Antibiotic) imported from China					Finished formulation (Antibiotic) imported from countries other than China				
2011	2012	2013	2014#		2011	2012	2013	2014#	
Qty in	48,441	67,921	26,541		25,851	25,851	3,89,78,811	4,69,54,631	3,03,11,109
units									
Value	0.28	0.20	0.18		0.27	106.30	65.66	54.86	
(Rs.in									
Creore)									
# Up to 20 November 2014.									

(b): The quality, safety and efficacy of the imported drugs including antibiotics used for manufacturing formulations in the country is

ensured through a system of registration of overseas manufacturing sites and drugs with the Drugs Controller General of India (DCGI). The registration of manufacturer is allowed only after (i) scrutiny of the requisite documents which are also required to be certified by our Embassy in the country of origin; and (ii) testing of the drug in a Government laboratory in India. The drugs imported from the registered manufacturers are also subjected to random testing at the time of import.

(c) & (d): The Government is aware of the existence of antimicrobial resistance in India and is concerned about its increasing incidence. A large number of studies conducted at various locations in India by ICMR and other health institutions from 2005 onwards found the presence of antimicrobial resistance in the country. Keeping in view the findings of these studies and other evidence, the Government of India constituted a National Task Force for containment of antimicrobial resistance in August 2010. The Task Force submitted its report in November, 2010 and recommended inter alia creating a National Surveillance System; initiating studies documenting prescriptions patterns and establishing a monitoring system; enforcing and enhancing regulatory provisions for the use of antibiotics in humans, veterinary and industrial use. A National Programme on containment of antimicrobial resistance is being implemented to propagate rational use of antibiotics in hospitals and training and capacity building of professionals in the relevant sectors. A separate Schedule (H1) has also been added to the Drugs and Cosmetics Rules on 30-08-2013 to restrict the indiscriminate sale of certain antibiotics, Anti TB drugs and habit forming drugs.

(e) Indian Medical Association (IMA) has initiated a campaign to spread awareness regarding the rational use of antibiotics. Further, IMA has constituted an Advisory Committee and based on the recommendation of the Committee, a module was prepared for the rational use of antibiotics. Medical Council of India has also stressed on the use of the generic name of drugs to ensure rational prescription by the physicians under the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.