

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

UNSTARRED QUESTION NO:1000

ANSWERED ON:12.08.2013

EXPORT OF PHARMACEUTICAL PRODUCTS

Majhi Shri Pradeep Kumar;Patel Shri Kishanbhai Vestabhai

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

(a) whether there is any proposal to boost the exports of pharmaceutical products by complying with the new procedural requirements of the European Union (EU) for the import of active pharmaceutical ingredients into the EU countries;

(b) if so, the details thereof;

(c) whether the Government has taken any action for complying with the new standards for export of bulk drugs into EU countries and if so, the details thereof;

(d) the details of the pharmaceutical products exported during each of the last three years and the current year particularly EU countries; and

(e) the extent to which the export of these products are likely to increase after complying with the new procedure requirements?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (DR. D. PURANDESWARI)

(a) to (c) : European Union had mandated through a Directive which came into effect from July 2, 2013 that every exported consignment of active pharmaceutical ingredients (APIs) from non-EU/non listed countries shall be supported by a certificate issued by competent authority of that country that the consignment conforms to standards of good manufacturing practices (GMPs) as laid down in the EU or equivalent thereof. After due consultations with relevant stakeholders, Government of India has nominated Central Drugs Standard Control Organization (CDSCO) as competent authority for the purpose of issuing the certificates.

(d) : Exports of drugs and pharmaceuticals (including APIs, formulations etc.) for the last 3 years and to EU countries are as follows :

Value in INR Cr				
India's exports of Pharmaceuticals				
	2010-11	2011-12	2012-13	#
Exports To EU	9125.16	12340.87	14336.86	
Total Exports	48875.82	63619.28	79,510	
India's global exports (INR Cr)				
Category	2009-10	2010-11	2011-12	2012-13#
Bulk Drugs	17414	180991	225561	23,392
Formulations	24,570	30,130	40,218	54,988
Herbals	571	646	845	1130
Total	42555	48875	63619	79,510

Source: CMIE/DGCIS # Figures for the year 2012-13 are provisional.

(e) By complying with EU Regulations in time, Indian Pharma Companies are expected to maintain a good rate of growth in their exports.