GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3437
TO BE ANSWERED ON THE 6th December, 2016

Indian Pharma Market

3437. SHRI GAJANAN KIRTIKAR:
SHRI S.R. VIJAYAKUMAR:
SHRI SUDHEER GUPTA:
SHRI ASHOK SHANKARRAO CHAVAN:
KUNWAR HARIBANSH SINGH:
DR. SUNIL BALIRAM GAIKWAD:
SHRI T. RADHAKRISHNAN:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the present overview of India's Pharma market as compared to the international pharma market;
(b) whether the Government has set a target of making Indian Pharma market a world leader by 2020;
(c) if so, the details thereof along with the assistance provided by the Government for improving manufacturing standard in the country and genetic as well as innovator market in pharmaceutical sector;
(d) whether the Government has reduced the time required for approval for new facilities to attract more investments in the country and if so, the details thereof; and
(e) the steps taken/being taken by the Government to check counterfeit drugs available in various parts of the country?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) : The Indian Pharmaceutical market is ranked 3rd globally in volume and 14th in terms of value, supplying around 10% of the total global production.
(b): The policies of the Government play a vital catalytic role in spurring the growth of the pharmaceutical industry in the country and strengthen it to become a global leader in the comity of nations in the global economy.
(c): In order to promote the Indian pharma sector to make it a global leader by 2020, the government is running various schemes like Cluster Development Programme for Pharma Sector (CDP-PS) for providing financial assistance for common facilities in pharma parks, for providing interest subsidy for improving Good Manufacturing Practices (GMP) compliance etc. The Government is also providing incentives for Research and Development.

The Government has also recently in order to provide level playing field to the domestic manufacturers has withdrawn custom duty exemption on certain categories of drugs/ medicines.

(d): Central Drugs Standard Control Organization (CDSCO) has recently introduced online portal "SUGAM" where applicant can apply online for various permissions/Licences such as permission for Import & Registration of drugs & Medical Devices & Diagnostics, Test License, Cosmetics, Ethics Committee Registration etc. The applicant can also track the status of submitted application, reply to the raised queries and can also upload essential documents for clearance of their applications.

(e): The term "Counterfeit drugs" is not defined under Drugs and Cosmetics Act, 1940. The Govt. of India has been taken/taking following steps to check the menace of spurious drugs in the country:

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable by setting of special Courts.

2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.

3. A Whistle Blower Scheme was announced by the Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. The scheme provides for suitably rewarding the informers for providing concrete information to the regulatory authorities in respect of movement of spurious drugs.

4. 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 (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.

5. The inspectorate staffs have been instructed to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

6. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 474 in 2016.

7. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

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