GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1294
TO BE ANSWERED ON 1st August, 2023

Production of quality medicines

1294 Dr. Kanimozhi NVN Somu:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the measures being taken by Government to produce quality medicines for all the people across the country;
(b) whether pharmaceutical industry in the country is working to address the challenges posed by climate change, biodiversity and environmental impact;
(c) if so, the details thereof; and
(d) the measures being taken by Government to ensure new and innovative means of drugs/treatment available in rural and tribal areas of Tamil Nadu?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): As per Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare, they have taken following regulatory measures to ensure the quality of medicines in the country: -

(i) 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.

(ii) States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(iii) The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.

(iv) To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

(v) The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

(vi) The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.

(b) & (c): As per Ministry of Environment, Forest and Climate Change; the Ministry has notified the Environment Impact Assessment (EIA) Notification, 2006, as amended from time to time, under the Environment (Protection) Act, 1986 which deals with the process to grant prior Environmental Clearance (EC). The projects listed in the schedule of this Notification require prior EC. Pharmaceutical industry is listed under schedule 5 (f). The sectoral Expert Appraisal Committee (EAC) comprising of different subject experts appraise the proposals as per the procedure laid down in the said Notification and prescribes various environmental safeguards as specific and general conditions while recommending for grant of EC. The project proponents are obliged to comply with these conditions as part of the EC.

(d): Government of India is implementing a number of schemes to ensure access to good quality treatment across the country. These include the Ayushmann Bharat -Pradhan Mantri Jan Arogya Yojana which provides for health cover of Rs.5 lakh per year for secondary and tertiary care hospitalisation. Further under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana, Generic medicines of good quality are being made available at prices that are 50% to 90% cheaper than branded medicines available in the market. As of 30. 06.2023, 9512 stores have been opened under the scheme including 910 stores in the state of Tamil Nadu.

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