

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION NO. †2078
TO BE ANSWERED ON 10th DECEMBER, 2021

Quality Medicines

†2078. **SHRI JASWANT SINGH BHABHOR:
SHRI NARANBHAI KACHHADIYA:
SHRI PARBATBHAI SAVABHAI PATEL:**

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

- (a) the measures being taken by the 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 the Government to ensure new and innovative means of drugs/treatment available in rural and tribal areas of Gujarat particularly in Dahod?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(DR. MANSUKH MANDAVIYA)**

(a): As per information provided by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare, the Organization regulates safety, efficacy and quality of the drugs, medical devices and Cosmetics as per the provisions of Drugs and Cosmetics Act 1940 & Rules made thereunder. CDSCO and Ministry of Health & Family Welfare from time to time have taken various measures for ensuring the quality of drugs in the country, such as:

- i. Drugs and Cosmetics Act, 1940 was amended in the year 2008 to provide stringent penalties for manufacturer of spurious and adulterated drugs and certain offences have also been made cognizable and non-bailable.
- ii. States/UTs were requested to set up Special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 33 states have already set up designated Special Courts.
- iii. Guidelines for taking action on samples of drugs declared as 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.

- iv. Number of sanctioned posts in CDSCO have been increased from 111 in 2008 to 492 in January, 2021.
- v. Testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.
- vi. In order to ensure efficacy of drugs, the Drugs and Cosmetics Rules 1945 have been amended in April, 2017 providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing License of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.
- vii. Drugs and Cosmetics Rules 1945 have been amended in October, 2017 making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by Drugs Inspectors of the Central Government and the State Government concerned. Further, the licensed manufacturing premises are to be inspected jointly by the Drugs Inspectors of Central Government and State Government concerned to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.
- viii. Drugs and Cosmetics Rules 1945 have been amended in April, 2018 making it mandatory that the applicants for all drugs shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.
- ix. Government has approved a proposal for strengthening the drug regulatory system in the country, both at the level of Central and the State Governments at a total expenditure of Rs. 1,750 crores.

(b) & (c): Ministry of Environment Forest and Climate Change, in consultation with the Central Pollution Control Board (CPCB), has notified discharge norms for pharmaceutical industries in January, 2020 under the Environment (Protection) Act, 1986. These norms are reviewed and revised periodically. The notified norms are enforced by the State Pollution Control Boards (SPCB) / Pollution Control Committees in the consent order (CTO-Consent to operate) issued under the Air Act (PCP), 1981 and the Water Act, 1974. Further the units are encouraged to reduce their waste water generation by technological advancement and reuse/recycle of wastewater.

All highly polluting 17 categories of industries, including bulk drugs and formulations (pharmaceutical) industry, have been directed to install online continuous effluent/emission monitoring systems (OCEMS). CPCB from time to time carries out surprise inspection of the industries for checking performance and operational status of pollution control measures adopted by the industries. During the inspection/manual monitoring, if any industry is found non-complying the norms, then closure direction is issued under section 5 of the Environment (Protection) Act, 1986 to the unit for rectification or up-gradation of Effluent Treatment Plant (ETP)/ Air Pollution Control devices (APCDs).

(d): Public Health being a State subject, the primary responsibility of supply of medicines and management of hospitals lies with the States/UTs concerned. However, the National Council for Clinical Establishments under the Ministry of Health & Family Welfare (MoH&FW) has approved a standard list of medical procedures and a standard template for costing of medical procedures and the same have been shared with all the States, including Gujarat, for appropriate action.

Further, in order to promote innovations and Research & Development so as to ensure that the new and innovative drugs are made available to all the citizens, exemption from price control under the Drugs (Prices Control) Order, 2013 (DPCO, 2013) is provided for a period of five years to the manufacturers producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970).
