GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 778
TO BE ANSWERED ON THE 29TH NOVEMBER 2024

Production of Quality Medicines

778. Shri K C Venugopal:

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 Government to ensure new and innovative means of drugs/treatment are made available in rural and tribal areas of Kerala?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken various measures to ensure quality, efficacy and safety of medicines manufactured in the country. The key measures are as stated below:

i. In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 400 premises. The firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality. complaints, criticality of the products etc. Based on findings of inspections, more than 300 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.
ii. Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. As per the amendment, the revised Good Manufacturing Practices and Requirements shall come into force for manufacturers for implementation as under:

Category of manufacturers [Based on turnover (INR)]	Time line for implementation
Large Six months manufacturers from the date (Turnover> of publication 250 crores)	Six months from the date of publication of these rules.

Small and Medium manufacturers (Turnover of these rules. 250 crores)	Twelve months from the date of publication of these rules.

iii. On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August. 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print Or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

iv. On 18.01.2022. the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

v. On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R, 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

vi. 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.

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

viii. 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.

ix. 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.

x. 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.

xi. Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

xii. Central government is providing regular Residential, regional training and workshops to CDSCO, State Drug Regulatory Authorities on Good Manufacturing Practices. In the training Financial Year 2023-24 CDSCO has trained 22854 persons while in F.Y 2024-25 so far 13007 persons have been trained.

xiii. Further, for strengthening the drug regulatory system in the country both at the Central and State level, the Government had approved Rs.1750 Crore. Out of this, Rs. 900 Crore was for strengthening the central drug regulatory structures and Rs. 850 Crore is for the Centrally Sponsored Scheme Strengthening of States' Drug Regulatory System (SSDRS) which envisages to strengthen the laboratory infrastructure and upgradation of existing State Drug Controller offices in States. So far under the SSDRS scheme, 17

New Drug Testing Labs have been constructed and 24 existing labs have been up-graded.

(b) to (c): Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Manufacturers are required to comply with Good Manufacturing Practices as prescribed under Schedule M to the Drugs Rules, 1945. As per the GMP requirement, the disposal of sewage and effluents (solid, liquid and gas) from the manufacturing area shall be in conformity with the requirements of the guidelines issued by the Environmental Pollution Control Board and all bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 2016

(d): As per the information provided by the State Government of Kerala, state has implemented several initiatives to ensure that tribal and rural population have access to new and innovative treatments as follows:

(1) Healthcare Infrastructure:

(i) Primary Health Centers (PHCs) and Community Health Centers (CHCs): The state has established a network of PHCs and CHCs in rural and tribal areas to provide basic healthcare services.
(ii) Sub-Centers: These smaller health facilities are located in remote areas to improve accessibility.
(iii) Mobile Medical Units: These units travel to remote areas to provide healthcare services, including vaccinations, check-ups, and treatment for common ailments.

(2) Specialized Healthcare:

(i) Telemedicine: The government has implemented telemedicine services to connect remote areas with specialists in urban centers. This allows for remote consultations and diagnosis.
(ii) Referral Systems: Patients in rural areas can be referred to specialized hospitals in cities for advanced treatment.
(iii) Ayurveda and Traditional Medicine: Kerala has a strong tradition of Ayurveda and other traditional medicine systems. The government supports the integration of these systems with modern medicine to provide holistic healthcare.

(3) Financial Assistance

(i) Health Insurance Schemes: The government provides health insurance schemes to cover the cost of medical treatment for low-income and vulnerable populations, including tribal communities.
(ii) Subsidized Medications: The government subsidizes essential medications to make them affordable for the poor.

(4) Awareness and Education:

(i) Health Education Campaigns: The government conducts health education campaigns to raise awareness about preventive healthcare, hygiene, and the importance of seeking timely medical attention.

(ii) Community Health Workers: Community health workers are trained to provide health education and promote preventive healthcare practices in rural areas.

(v) Specific Initiatives for Tribal Populations:

(i) Tribal Health Clinics: These clinics provide specialized care for tribal communities, addressing their unique health needs.
(ii) Nutrition Programs: The government implements nutrition programs to address malnutrition and other nutritional deficiencies among tribal populations.
(iii) Mental Health Services: Mental health services are provided in tribal areas to address issues like depression, anxiety, and substance abuse. By implementing these measures, the Kerala government aims to bridge the healthcare gap between urban and rural areas and ensure that all citizens, including tribal and rural populations, have access to quality healthcare services.

The role of Non-Governmental Organizations (NGOs) and the private sector in improving healthcare in tribal areas is also significant. They focus on providing free or subsidized healthcare, including mental health, disability support, and maternal health. These organizations work to improve healthcare access in rural and tribal areas, often complementing government efforts. Providing primary healthcare camps, nutrition kits, medical aid, and safe drinking water in rural areas.

Apart from the above, Government of India launched 'Jan Aushadhi' Scheme in 2008 with an objective of making quality generic medicines available at affordable prices to all citizens, especially the poor and the deprived ones. The Scheme was revamped and named as ‘Pradhan Mantri Jan Aushadhi Yojana’ (PMJAY) in Sept.2015 and further renamed as ’Pradhan Mantri Bhartiya Janaushadhi Pariyojana' (PMBJP) in December 2016. Under the Scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are opened to provide quality generic medicines at affordable prices. Objectives of the Scheme are as follows:

(a) To make available quality medicines consumables and surgical items at affordable prices for all and thereby reduce out of pocket expenditure of consumers/patients.
(b) To popularize generic medicines among the masses and dispel the prevalent notion that low priced generic medicines are of inferior quality or are less effective.
(c) Generate employment by engaging individual entrepreneurs in the opening of PMBJP Kendras.

Under the scheme, district-wise list of Jan Aushadhi Kendras opened in the State of Kerala is enclosed as Annexure-I.

Annexure-I

District wise list of Jan Aushadhi Kendras opened in Kerala		
Sl. No.	**Name of the District**	**No. of Jan Aushadhi Kendras**
1	Alappuzha	118
2	Ernakulam	171
3	Idukki	40
4	Kannur	79
5	Kasaragod	37
6	Kollam	87
7	Kottayam	96
8	Kozhikode	127
9	Malappuram	156
10	Palakkad	140
11	Pathanamthitta	50
12	Thiruvananthapuram	130
13	Thrissur	185
14	Wayanad	27
Total		**1443**

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