GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
STARRED QUESTION NO. 276
TO BE ANSWERED ON THE 9TH AUGUST, 2024

REGULATION OF DRUGS

***276 SHRI SHRIRANG APPA CHANDU BARNE:**
SHRI ARVIND GANPAT SAWANT:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the position of India as drugs producer and exporter of drugs in the world;

(b) whether there is a need for world-class drugs regulations to draw a roadmap to achieve global standards, if so, the details thereof along with the response of the Central Government thereto and the action taken in this regard;

(c) whether States are an integral part of the regulatory value chain and there is also a need to work together to enhance the skills and capabilities of the States, if so, the details thereof, State/UT-wise;

(d) the steps taken/proposed to be taken by the Central Government to align with the quality standards of the Central Government; and

(e) whether the Central Government has reviewed the regulation of drugs, cosmetics, and medical devices with a view to achieve global standards in India′s pharmaceutical industry and if so, the details thereof, State/UT-wise?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (e) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 276 FOR 9TH AUGUST, 2024

(a) Indian Pharmaceuticals Industry is 3rd largest by volume and 13th largest by value in the world producing more than 60,000 generic drugs across 60 therapeutic categories.

(b) & (d) Under Drugs and Cosmetics Act, 1940 and Rules made thereunder, the regulatory control over the drugs imported into the country is exercised by the Central Government through the Central Drugs Standard Control Organization (CDSCO).

Under the said Act and Rules the regulatory control over the manufacture and sale of drugs is exercised through a system of licensing and inspection by the State Licensing Authorities appointed by the State Governments. Licensee is required to comply with all the conditions of license including Good manufacturing practices (GMP) as prescribed under Drugs Rules, 1945. State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law.

CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to have a robust drug regulatory system in the country. The key measures are as stated below;

(i). 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.

(ii). 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.

(iii). 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.

(iv). 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.

(v). 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.

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

(vii). The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

(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.

(c) Yes, States are an integral part of the regulatory value chain. 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.

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 up-gradation of existing State Drug Controller offices in States. So far under the SSDRS scheme, funds to the tune to Rs. 699.28 Crore have been released as part of the Central Share.

Central government has also conducted 22 training programs for CDSCO and State Drug Control officials in the Financial Year 2023-24.

(e) The Central Government reviews the regulation of Drugs, Cosmetics and medical devices, from time to time, for appropriate amendments to ensure Quality, Safety, Efficacy of Drugs, Cosmetics and Medical Device manufactured and imported in the country.

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