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

LOK SABHA
UNSTARRED QUESTION NO. 3790
TO BE ANSWERED ON 11TH AUGUST, 2023

MANUFACTURING OF SUB-STANDARD DRUGS

3790: SHRI NATARAJAN P.R.:

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

(a) whether the Government proposes to amend the existing rules to include stringent punishment for manufacturers and suppliers of adulterated drugs in the country;
(b) if so, the details thereof and if not, the reasons therefor; and
(c) the steps taken/proposed to be taken by the Government to control the manufacturing of sub-standard drugs in the country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 & its Rules through a system of licensing and inspection by State Licensing Authorities appointed by respective State Governments. Licensee is required to comply with all the conditions of license as prescribed under Drugs & Cosmetics Rules and the State Licensing Authorities are empowered to take action.

The Drugs and Cosmetics Act has provisions for penalties in case of contraventions to various provisions of the said Act and Rules. The Act was amended by way of Drugs & Cosmetics (Amendment) Act 2008 to provide for more stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

Further, CDSCO and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the quality of medicines in the country:-

(i). States/ UTs have set up special Courts for trial of offences under the Drugs and

Cosmetics Act for speedy disposal.

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

(iii). 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.

(iv). 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.

(v). 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.

(vi). CDSCO 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.

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