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

LOK SABHA
UNSTARRED QUESTION NO. 1820
TO BE ANSWERED ON 27th JULY, 2018

PRESCRIBING OF GENERIC DRUGS

1820. SHRI MD. BADARUDDOZA KHAN:
SHRI MUTHAMSETTI SRINIVASA RAO(AVANTHI):
SHRI MOHD. SALIM:
SHRI SUMEDHANAND SARSWATI:
SHRI OM PRAKASH YADAV:
SHRIMATI SANTOSH AHLAWAT:

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

(a) whether Government is making it mandatory for doctors to prescribe generic medicines and if so, the details thereof;

(b) whether the Government has received any complaints in which doctors have refused to prescribe generic medicine to the patient and if so, the details thereof along with action taken thereon;

(c) whether doctors are reluctant to prescribe generic drugs for want of quality assurance and if so, the steps taken to assure the quality of generic drugs;

(d) whether some of the doctors' community are against this regulation, if so, the reasons therefor; and

(e) whether the Government is also contemplating to bring a law requiring doctors to prescribe generic drugs and if so, the details thereof and the time by which the said law is likely to be enacted?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (e): The professional conduct of doctors in India is regulated by the Medical Council of India (MCI) and the respective State Medical Councils in accordance with the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Clause 1.5 of the said regulations prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs.

Further, Manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules made thereunder through a system of licensing and inspection. License for manufacturing, sale and distribution of drugs are granted by State Licensing Authorities appointed by respective State Governments. Drug manufactured in the country, irrespective of whether branded or generic, are required to comply with the same standards as prescribed in the said Act and Rules for their quality. The State Licensing Authorities are empowered to take action against violations of any of the above requirements.

CDSCO under the Ministry of Health and Family Welfare has taken various measures to ensure the quality of generic medicines in the country which include:

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. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.

III. Guidelines for taking action on samples of drugs declared 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. The inspectorate staffs have been instructed to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

V. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 510 in 2018.

VI. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

VII. On 3.4.2017, in order 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 licence of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

VIII. On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) 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.