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

LOK SABHA
UNSTARRED QUESTION NO. 3300
TO BE ANSWERED ON 17TH DECEMBER, 2021

ACUTE LYMPHOBLASTIC LEUKAEMIA

3300. SHRI JAYANT SINHA:

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

(a) whether the Government proposes to take action to enhance the quality of the native Biogenerics used for treatment of Acute Lymphoblastic Leukaemia (ALL);
(b) if so, the details thereof; and
(c) the initiative taken by the Government to do a quality-check, and enhance the quality of cancer drugs available in the country?

ANSWER

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

(a) and (b):Manufacturing, sales and distribution of drugs in the country are regulated under the provision of Drugs & Cosmetic Act, 1940 and Drugs Rules,1945. It is made there under through a system of Licencing and Inspection. License for sale and distribution of drugs are granted by State Licensing Authorities appointed by respective State Governments. The Licensees are required to comply with all the conditions of license including the conditions that the licensee is required to comply with the requirement of Good Manufacturing Practices as prescribed in Schedule M of the Rules and before release of the product in the market each batch is required to be tested to ensure the quality of the drug.

The State Licensing Authorities are empowered to take action against any violation of the conditions of licenses.

Various drugs are approved for treatment of Acute Lymphoblastic Leukaemia (ALL). However, there is no such terminology like Biogenerics in the said Act and Rules thereunder.

(c): The Central Drugs Standard Control Organisation(CDSCO) and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines in the country.

The details are provided below,

1) 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.

2) 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.

3) 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.

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

5) 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.

6) On 27.10.2017, 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 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.

7) On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.

8) Draft Rules have been published vide GSR 999 (E), dated 5th 10.2018 to amend the Schedule M of the Drugs and Cosmetics Rules, 1945 to make it more comprehensive at par with the WHO-GMP guidelines

9) The Government had 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.1750 crores. Out of this, Rs. 900 crores were for strengthening the central drug regulatory structures and Rs.850 crores were for strengthening the drug regulatory system in the States. During the years 2016-17 and 2017-18, Rs. 128.39 crore had been released under the Central component whereas Rs. 87.90 crore had been allocated during 2018-19 under this component. Under the State component, Rs. 81.36 crore had been released during 2016-17 and 2017-18 whereas Rs. 206 crores had been allocated during 2018-19 under this component.