**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS AND FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 430
TO BE ANSWERED ON THE 04th February, 2020

## BIS Standard for Chemicals

**430. SHRI BHAGWANTH KHUBA:**
**SHRI DILIP SAIKIA:**
**SHRI RAMESH CHANDER KAUSHIK:**
**SHRI TAPIR GAO:**

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the details of steps taken by department of Pharmaceuticals for standardization and quality improvement;
(b) whether it is a fact that many chemicals produced and imported in the country are not having BIS standards;
(c) if so, the details thereof;
(d) whether the Government has recently made BIS standard mandatory for some chemicals; and
(e) if so, the details thereof?

## ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS**
**(SHRI D. V. SADANANDA GOWDA)**

(a): The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act & Rules 1945 made thereunder 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, 1945 and State Licensing Authorities are empowered to take action on violation of any condition of such licenses including prosecution in appropriate Court of law. Central Drugs Standard Control Organization (CDSCO) and Ministry of Health & Family Welfare has taken various measure at time to time to ensure quality of drugs in the country.

Major such reforms are as under:

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, 32 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 number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 492 in 2019.

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

6. 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.

7. 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. The licensed manufacturing premises shall 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.

8. On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), 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.

The Government has also 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 crore is for strengthening the central drug regulatory structures and Rs.850 crore is for strengthening the drug regulatory system in the States. During the years 2016-17 and 17-18, Rs. 128.39 crore has been released under the Central component whereas Rs. 87.90 crore has been allocated during 2018-19 under this component. Rs. 82.90 crore was allocated during the year 2019-20. Under the State component, Rs. 81.36 crore has been released during 2016-17 and 17-18 whereas Rs. 206 crore was allocated during 2018-19 under this component.

(b) & (c): The chemicals sector is de-licensed. The BIS standards of majority of chemicals & petrochemicals are voluntary in nature. Bureau of Indian Standards (BIS) has formulated approximately 853 standards on chemical & chemical products. Further there are many chemicals and chemical products produced and imported in the country, which are not having BIS standards.

(d) & (e): The Government has recently made BIS Standards mandatory for Caustic Soda, Acetic Acid, Aniline, Methanol and Poly Aluminium Chloride to protect human health, environment, national security and to prevent unfair trade practices.

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