

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

RAJYA SABHA
UNSTARRED QUESTION NO. 2758
TO BE ANSWERED ON 19th March, 2021

Quality improvement and standardization for chemicals

2758 Shri M.V. Shreyams Kumar:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) the details of steps taken by the 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 Government has recently made BIS standard mandatory for some chemicals; and
- (e) if so, the details thereof?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & 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 measures from 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 the 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.

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

(d) & (e): As per Department of Chemicals and Petrochemicals (DCPC), BIS standards of majority of chemicals and petrochemicals are voluntary in nature. Sometimes, inferior and spurious chemicals are supplied by local manufacturer or imported into India, which do not meet the quality parameters laid down by BIS standard. To address the issue, DCPC initiated exercise to make standards mandatory so that both domestic manufacturers and overseas meet the BIS parameters. The standards of chemicals and petrochemicals are made mandatory under section 16 of BIS Act, 2016 and Quality Control Orders are accordingly issued. So far, DCPC has issued 34 Quality Control Orders. The Government has recently made BIS Standards mandatory for Caustic Soda, Acetic Acid, Methanol and Boric Acid to protect human health, environment, national security and to prevent unfair trade practices.
