GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. **512**
TO BE ANSWERED ON THE **7th February, 2023**

Drugs manufacturing companies

512 # Shri Neeraj Dangi:

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

(a) the number of drugs manufacturing companies, including registered and operational multinational and foreign companies in the country;
(b) the company-wise quantum of drugs manufactured during the last three years and the current year; and
(c) whether Government has any mechanism to regulate and monitor the manufacturing and marketing of drugs by these companies, if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): As per information received from Central Drugs Standard Control Organization (CDSCO) under the Department of Health & Family Welfare (DoHFW), the number of drug manufacturing units in the country is 10,706 as on 31-12-2022.

(b): The Department of Pharmaceuticals do not maintain the details of company-wise quantum of drugs manufactured.

(c): As per the information received from CDSCO under DoHFW, under the Drug and Cosmetics Act, 1940 and rules thereunder, the manufacture, sale and distribution of drugs in the country is primarily regulated by the State Drug Control Authorities while control over drugs imported into the country is exercised by the Central Government through CDSCO. The regulatory control over the manufacture and sale of the drugs is exercised through a system of licensing and inspection by the State Licensing Authorities appointed by the State Governments. Licensee is required to comply with all the condition of license as prescribed under Drugs Rules, 1945 and State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law. CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines in the country and the same is given at **Annexure.**

Annexure

Major various regulatory measures taken by CDSCO to ensure the quality of medicines in the country

(i) On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R.823(E) which would come into force on 1st of August, 2023 providing that the manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication. The stored data or information referred to in sub-rule (6) shall include the following particulars, namely:

(a) unique product identification code;
(b) proper and generic name of the drug;
(c) brand name;
(d) name and address of the manufacturer;
(e) batch number;
(f) date of manufacturing;
(g) date of expiry; and
(h) Manufacturing licence number.

(ii) On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including Unique product identification code, Batch No, MFG date, expiry date, etc.

(iii) The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 492 till January 2022. Further, 220 posts have been created on 16-06-2022 and 219 posts have been created on dated 13.07.2022.

(iv) On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that w.e.f. 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these rules.

(v) On 6.11.2019, the Drugs Rules, 1945 were amended vide Gazette notification no. G.S.R.828(E), providing that in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the Licensing Authority to the effect that to the best of his knowledge based on search in trademarks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market with effective from 06.11.2019.

(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 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.

(viii) 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 license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

(ix) 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.

(x) 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.

(xi) States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 33 States have already set up designated special Courts.

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