GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 2265
TO BE ANSWERED ON THE 21st March, 2023

Quality of pharmaceuticals

2265 Shri Sushil Kumar Gupta:

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

(a) whether Government is taking any new initiatives for ensuring that pharmaceuticals manufactured in the country and consumed by domestic and international consumers are of the highest quality and adhere to standard global manufacturing protocols; and
(b) if so, the details in this regard?

ANSWER

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

(a) & (b): The regulations governing the quality of pharmaceuticals fall under the ambit of Central Drugs Standards and Control Organisation (CDSCO) under the D/o Health and Family Welfare (DoHFW). As per the information received from DoHFW, the Manufacturing, sale and distribution of drugs in the country is regulated under the provisions of the Drugs & Cosmetics Act, 1940 and Rules 1945 through a system of licensing and inspection. The Second Schedule of the said Act prescribes the standards to be complied with by imported drugs and by drugs manufactured by manufacturers for sale, stocked or exhibited for sale or distributed. The manufacturers are also required to comply with the requirements of Good Manufacturing Practices prescribed under the Schedule-M of the Drugs Rules 1945 so as to ensure that the drugs manufactured in the country conform to the standards prescribed. Further, the CDSCO has taken various regulatory measures to ensure the quality of medicines in the country. Major such reforms are given in **Annexure**.

Annexure

1. **Amendment in Drugs Rules for mandating Bar code or QR code on the label of top 300 brands**

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 Top 300 brands 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:

(i) unique product identification code;
(ii) proper and generic name of the drug;
(iii) brand name;
(iv) name and address of the manufacturer;
(v) batch number;
(vi) date of manufacturing;
(vii) date of expiry; and
(viii) Manufacturing licence number."

2. **Amendment in Drugs Rules for mandating QR code for active pharmaceutical ingredients**

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, Exp. Date etc.

3. **Increase of sanctioned posts in CDSCO**

The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 478 till January 2022 and additional 220 posts have recently been created on 27-06-2022.

4. **Marketer responsible for quality of drugs and regulatory compliances**

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.

5. **Undertaking by applicant for brand name or trade name of drugs to avoid confusion or deception in the market**

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.

6. **Strengthening of testing capacities of Central Drugs Testing Laboratories**

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

7. **Submission of evidence of stability, safety of excipients of drugs by applicant to State Licensing Authority.**

On 10.04.2018, the Drugs and Cosmetics Rules, 1945 (D & C 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 (SLA) before grant of product manufacturing license by the Authority.

8. **Draft revised Schedule M**

Draft Rules have been published vide GSR 999 (E), dated 05.10.2018 to amend the Schedule M of the D & C Rules, 1945 to make it more comprehensive at par with the WHO-GMP guidelines.

9. **Submission of bioequivalence study data for grant of manufacturing license**

On 3.4.2017, in order to ensure efficacy of drugs, the D & C Rules 1945 have been amended providing that applicant shall submit the results 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.

10. **Joint Inspections by Central and State Licensing Authorities before grant of manufacturing license**

On 27.10.2017, the D& C 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.

11. **Provisions for stringent penalties for manufacture of spurious and adulterated drugs**

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.

12. **Special Courts for trial of offences**

The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act 1940 for speedy disposal. So far, 33 States have already set up designated special Courts.

13. **Proposal for strengthening of Drug Regulatory System.**

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 crore was for strengthening the central drug regulatory structures and Rs.850 crore was for strengthening the drug regulatory system in the States. During the years 2016-17 and 17-18, Rs. 128.39 crore was released under the Central component whereas Rs. 87.90 crore was 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 was released during 2016-17 and 17-18 whereas Rs. 206 crore was allocated during 2018-19 under this component.

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