GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 633
TO BE ANSWERED ON THE 9TH DECEMBER, 2022

Quality of Drugs

633. SHRI P.V. MIDHUN REDDY:
SHRI ADALA PRABHAKARA REDDY:

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

(a) whether the Government has received complaints from countries such as Vietnam, Sri Lanka, Ghana, Mozambique and Nigeria over the quality of drugs being exported by the Indian pharmaceutical industry to them;
(b) if so, the remedial measures taken to address these complaints;
(c) the list of measures taken/likely to be taken by the Government to prevent the export of adulterated drugs following the World Health Organisation's alert; and
(d) the steps taken by the Government to improve the quality of drugs manufactured in India?

ANSWER

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

(a): As per information received from Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare, isolated complaints on quality related issues of drugs exported by the Indian Pharmaceutical companies have been received from some foreign countries like Vietnam and Sri Lanka.

(b) to (d): As and when complaints are received by CDSCO, the same are investigated in consultation with the State Licensing Authorities (SLAs). Based on the investigations, SLAs take suitable action under the provisions of the Drugs and Cosmetics Act, 1940 & Rules. In case of manufacturing drugs for exports, the manufacturers are required to obtain license from the concerned State Licensing Authority (SLA) and the same are required to be manufactured in accordance to the conditions of license under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. Further, in case of drugs meant for export, the manufacturers are also required to meet the requirements of importing country. CDSCO and the Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines in the country. The major reforms are as under:

(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 CDSCO has been increased from 111 in 2008 to 478 till January 2022 and 220 posts have recently been created on 27-06-2022.

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

(ix) 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.

(x) 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.

(xi) 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.

(xii) 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.

(xiii) 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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