

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

RAJYA SABHA  
UNSTARRED QUESTION No. 655  
TO BE ANSWERED ON THE 13<sup>TH</sup> DECEMBER, 2022

**Measures to ensure safety, quality and standards in pharma manufacturing**

**655 Smt. Jebi Mather Hisham:**

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

- (a) whether Government has double-checked the claim that cough syrup that caused death of dozens of children in Gambia has not been marketed in India;
- (b) whether Government has instituted a high-level enquiry on how a syrup adulterated with diethylene glycol and ethylene glycol could be given export permits;
- (c) whether Government will revamp the legal framework and regulatory mechanism on safety, quality and standards of pharma manufacturing in the backdrop of such deaths, if so, the details thereof;
- (d) whether adulterated cough syrup export impacted the Indian pharma business in international market; and
- (e) the measures taken to avert such incidents in the future?

**ANSWER**

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

---

(a) & (b): As per information received from Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare, CDSCO in coordination with State Drug Controller, Haryana carried out investigation at M/s Maiden Pharmaceuticals Limited 81, HSIDC Industrial Area, Kundli 131028, Dist. Sonapat (Haryana), to ascertain the facts that allegedly led to the death of 66 children in Gambia.

In this regard, during the joint investigation undertaken by CDSCO and State Drug Controller, Haryana, it was revealed that the State Drug Controller, Haryana had given licenses to the said company for manufacture of these four drugs namely Promethazine Oral Solution BP, KOFEXMALIN Baby Cough Syrup, MaKOFF Baby Cough syrup and MaGrip n Cold Syrup, for *export purpose* only. These 04 drugs are not licensed for manufacture and sale in India and the said drugs are not marketed or distributed in India.

Further, control samples of the aforementioned drugs were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) Chandigarh by the investigating team. As per report of the Government Analyst, the samples have been declared to be of standard quality. The said samples were also found negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

Based on investigations conducted, State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma on 7.10.2022 under Rule 85(2) of the Drugs Rules, 1945. Further,

an order under section 22(1)(d) of the Drugs and Cosmetics Act, 1940 issued to M/s Maiden Pharmaceuticals Limited, Sonapat, Haryana on 11.10.2022 stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonapat with immediate effect in public interest.

(c) to (e): 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 condition of license as prescribed under Drugs & Cosmetics 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. 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. Further, as already mentioned in part (a) & (b), the samples of cough syrup drawn for test and analysis were declared to be of Standard Quality by the Government Analyst of RDTL Chandigarh.

CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines manufactured 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.

There have been reports both in domestic and international media on the incident. There is no observable impact on the Indian Pharma Export in the past few months, that can be attributed to this incident.