GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO.1562
TO BE ANSWERED ON 20th DECEMBER, 2022

ADULTERATED COUGH SYRUP

1562: SHRI K.C. VENUGOPAL:
SHRI VIVEK K. TANKHA:
SHRI MUKUL BALKRISHNA WASNIK:
SHRI DIGVIJAYA SINGH:
DR. AMEE YAJNIK:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has conducted an investigation of the cough syrup manufactured in Haryana that killed children in Gambia;
(b) if so, the findings thereof;
(c) whether Government is aware of the death of 12 children in Jammu in 2019 and 13 children in Himachal Pradesh in 2020 due to adulterated cough syrup;
(d) the steps taken/being taken by Government to strengthen its drug regulation policy in light of these incidents; and
(e) whether Government believes that these incidents may hinder India's medicinal trade relations with foreign countries and if so, the measures it intends to take to alleviate the impact?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (e): Central Drugs Standard Control Organisation (CDSCO) in coordination with State Drug Controller has carried out investigation at the concerned manufacturing unit, to ascertain the facts of the matter reported by WHO.

Joint investigation was conducted by CDSCO and State Drug Controller during which it was revealed that the State Drug Controller had given licenses to the said company for manufacture of four drugs, for export purpose only. These drugs were not licensed for manufacture and sale in India, and the said drugs are not marketed or distributed in India. Control samples of the aforementioned drugs from the manufacturing unit were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) of CDSCO by the

investigating team. As per report of the Government Analyst, the samples have been declared to be of standard quality.

Based on investigations conducted, which revealed violation of Good Manufacturing Practices (GMP), State Drugs Controller issued show cause notice to M/s Maiden Pharma under Rule 85(2) of the Drugs Rules, 1945 and order has been issued for stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonipat with immediate effect for violation of GMP.

There is a regulatory framework under the provisions of Drugs and Cosmetics Act and Rules to regulate drugs, medical devices and cosmetics. Manufacture, sale and distribution of Drugs is primarily regulated by the State Licensing Authorities (appointed by respective State Governments) through a system of licensing and inspection while the Central Licensing Authority is responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs etc. Isolated cases of allegedly contaminated cough syrup leading to death in Children have been reported in the past.

The cases concerning quality or safety of drugs when reported, the matter is taken up with the concerned State Licensing Authority (SLA) in order to take necessary action under the provisions of Drugs and Cosmetics Act 1940 and its Rules. The State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law. The Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

******