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

RAJYA SABHA
UNSTARRED QUESTION NO.3159
TO BE ANSWERED ON 23RD MARCH, 2021

ILLEGAL CANCER DRUGS FROM BANGLADESH

3159 SMT. SHANTA CHHETRI:

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

(a) whether the Ministry is aware that Illegal cancer drugs from Bangladesh are flooding local market;

(b) whether a thriving grey market of fake and unapproved copies of Big Pharma's oncology and hepatology medicines are being sold in Indian market at cheap rates causing loss to domestic companies and MNCs, which manufacture these medicines;

(c) with the safety and efficacy of these capsules not known, as they are not imported through the legal route, whether any steps have been taken to rectify the on going wrong doing; and

(d) if so, the details thereof if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) & (b): Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare has received complaint from Organization of Pharmaceutical producers in India (OPPI) stating that respective innovative products of their member companies are being imported illegally into India from Bangladesh without a valid license. After examination, action has been taken as per the provisions of Drugs and Cosmetic Act, 1940 and rules made there under.

Further, the manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

(c) & (d): For import of any drug from the foreign manufacturing site, the drugs are required to be registered as well as import license is required to be obtained from CDSCO under the provisions of the Drugs and Cosmetics Act, 1940 and rules made there under.

For import of any new drug, the applicant is also required to obtain New Drugs Permission under the New Drugs and Clinical Trials Rules 2019 from CDSCO prior to Import Registration and licence by filing application with safety and efficacy data as per the requirements prescribed under the said Rules.

Safety and efficacy of any drug, if imported without the necessary permission/licence will remain questionable and such import is subject to action as per the provisions of Drugs and Cosmetics Act and Rules there under.

The port offices of CDSCO verify the consignments randomly at the port and draw samples for testing of drugs from imported consignments as per the defined criteria.