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

LOK SABHA UNSTARRED QUESTION NO.5609 TO BE ANSWERED ON 26TH JULY, 2019

MARKETING OF UNAPPROVED DRUGS

5609. SHRI ANUBHAV MOHANTY: SHRI PINAKI MISRA:

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

(a) whether some of the leading drug manufacturing companies are taking refuge under the loopholes in the Drugs and Cosmetics Act and are marketing drugs manufactured by different companies which are not approved for human use and if so, the details thereof;

(b) whether his Ministry and the Drug Controller General of India conducted raids on about 15 facilities in the past few months and have issued show cause notices to them for different violations;

(c) if so, the details thereof indicating such companies which were raided in the past few months and were issued with show cause notices;

(d) whether it is a fact that some of these drugs are not approved for human consumption anywhere in the world and if so, the details thereof; and

(e) whether during the recent raids on the premises of some leading companies the regulatory Inspectors found raw materials used in the making of these medicines were actually imported from China as food items and if so, the details thereof and the corrective steps taken by the Government in this regard?

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

(a) to (e): Central Drugs Standard Control Organisation (CDSCO) has conducted raids/ investigations at various manufacturing sites in the past few months. Investigations have revealed that two manufacturers were manufacturing new drugs without the approval of CDSCO which were being marketed by different manufacturing companies for which show-cause notices were issued.

Three Manufacturers, one each from Daman and Diu, Tamil Nadu and Himachal Pradesh, were found indulging in manufacturing of drug, Enclomiphene Citrate, which is not approved for human consumption anywhere in the world.

One manufacturer was found manufacturing drugs with raw materials which were imported from China as food items and action under the provision of Drugs and Cosmetics Act and Rules has been initiated.