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

LOK SABHA UNSTARRED QUESTION NO.1159 TO BE ANSWERED ON 28TH JUNE, 2019

GUIDELINES FOR DISTRIBUTION PRACTICES

1159. SHRI SYED IMTIAZ JALEEL: SHRI ASADUDDIN OWAISI:

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

(a) whether the Government proposes stringent guidelines for distribution practices for drug companies;

(b) if so, the details thereof;

(c) whether these guidelines have been approved by Drug Technical Advisory Board (DTAB);

(d) if so, the details thereof and if not, the time by which these are likely to be approved by DTAB; and

(e) the extent to which consumers are likely to be benefited after enforcement of these guidelines?

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

(a) to (d): Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare responsible for ensuring quality, safety and efficacy of drugs in the country had issued a public notice on 25.09.2018 inviting comments from all stake holders on draft guidelines on Good Distribution Practices (GDP) for pharmaceutical products.

Drugs Technical Advisory Board (DTAB) in its 81st and 83rd meetings held on 29.11.2018 and 11.06.2019 respectively, deliberated and agreed to incorporate the said guidelines as a separate Schedule in the Drugs and Cosmetics Rules, 1945.

(e): Good Distribution Practices (GDP) is one of the important components for ensuring quality, safety and efficacy of drugs in the entire supply chain.