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

LOK SABHA UNSTARRED QUESTION NO. 3651 TO BE ANSWERED ON 16TH MARCH, 2018

BEDAQUILINE DRUG FOR DR-TB PATIENTS

3651. SHRI DHARAM VIRA:

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

(a) whether the Government has introduced the new drug Bedaquiline for Drug Resistant-TB;

(b) if so, the details of its availability in the States along with the details of the number of patients who have benefited from the new drug;

(c) whether it is true that Bedaquiline is not available in all States;

(d) if so, the steps taken by the Government to ensure that the States provide Bedaquiline to every Drug Resistant-TB patient; and

(e) whether the Government plans to make available Bedaquiline across the country, if so, the details thereof?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

(a) to (e): Yes. In the absence of phase 3 clinical trials, Drug Controller General (India) has approved use of Bedaquiline (BDQ) under Conditional Access Programme (CAP) based on US FDA & European Medicine Agency approval. Bedaquiline is to be given only to eligible patients as per the criteria laid down under the Guidelines for Management of Drug Resistant TB in India-2017. Accordingly, Revised National TB Control Programme (RNTCP) introduced Bedaquiline initially in 5 states i.e. Assam, Delhi, Gujarat, Maharashtra and Tamil Nadu. Till the end of Feb, 2018, 1059 patients are on Bedaquiline containing regimen.

In view of availability of enough drug to implement Bedaquiline containing regimen, rest of the States/UTs have been given guidance for expansion of Bedaquiline throughout country in all Nodal Drug Resistant TB (DRTB) Centres as per aforesaid guidelines.