Response from Central TB Division:

1. Please provide reasons for the shortage of stocks for the drug Delamanid as reported by Hindu Business Line.

Ans: NTEP has introduced a new drug, Delamanid, to be used under the programmatic conditions during Sep 2018. Out of total 400 drug courses received through donation from manufacturer, 398 courses are already distributed to 21 states. Programme division had initiated the process of procurement of Delamanid on 27 th Feb 2019 along with all other drugs for procurement of the drug. Indent to Central Medical Services Society (CMSS) was submitted by Programme Division on 28 th March 2019. CMSS issued LOA to M/s Mylan on 15th Jan 2020 for 1384 Patient courses. The 1st tranche of the supplies is scheduled to arrive the consignees by end March/ early April 2020. In the interim to tide over the crises situation programme division is in the process of securing 100 patient courses from M/s Mylan.

2. Please provide all correspondence between the Government of India, and Ostuka and Mylan regarding the purchase of Delamanid stock.

Ans: For NTEP, procurement (purchase) of all Anti TB drugs including Delamanid is done by Central Medical Services Society (CMSS), an autonomous body under MoHFW. Hence, no correspondence between the Government of India and Otsuka and Mylan regarding purchase of Delamanid stock is available with the programme division.

3. Please provide reasons for delay in finalizing the treatment protocol for combination of Bedaquiline and Delamanid.

Ans: Policies under the programme are implemented as per the recommendations of national technical expert committees for various component of programme based on the collective wisdom and deliberation on available evidences. Combined use of both Bedaquiline and Delamanid under programmatic condition is yet not recommended by the national expert group. Moreover, a rapid communication published by WHO in Dec'2019, combined use of Bedaquiline and Delamanid is not approved by WHO even. However, there are certain request received to the Division for requirement of combined use of drugs in specific situation, where in, effective regimen cannot be designed without the combined use of both the drugs. In such situation, programme has approved the use under 'off-label' situation, case to case basis, after seeking concurrence of the experts.

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