

**TAKING ON TB: ON NEW ANTI-TUBERCULOSIS DRUG****Context:**

- ▶▶ The anti-tuberculosis drug Pretomanid was recently approved by the U.S. Food and Drug Administration that will be a game changer for treating people with extensively drug-resistant TB.

**Introduction:**

- ▶▶ Tuberculosis (TB) remains the biggest killer disease in India, outnumbering all other infectious diseases put together this despite our battle against it from 1962, when the National TB Programme (NTP) was launched.
- ▶▶ In 1978, the Expanded Programme on Immunisation (EPI) began, giving BCG to all babies soon after birth and achieving more than 90% coverage.
- ▶▶ Yet, when evaluated in 1990, the NTP and the EPI had not reduced India's TB burden.
- ▶▶ In 1993, the Revised National TB Control Programme (RNTCP) was launched, offering free diagnosis and treatment for patients, rescuing them from otherwise sure death.

**What is Tuberculosis?**

- ▶▶ Tuberculosis, generally called TB is an infectious airborne bacterial disease caused by Mycobacterium tuberculosis, which most commonly affects the lungs but can also damage other parts of the body.
- ▶▶ There are two TB-related conditions:
- ▶▶ **Latent TB** - the bacteria remain in the body in an inactive state. They cause no symptoms and are not contagious, but they can become active.
- ▶▶ **Active TB** - the bacteria do cause symptoms and can be transmitted to others

**Global Tuberculosis Report:**

- ▶▶ Global tuberculosis report was published by every year since 1997.
- ▶▶ The main aim of the report is to provide a comprehensive and up-to-date assessment of the TB epidemic, and of progress in prevention, diagnosis and treatment of the disease at global, regional and country levels.
- ▶▶ This is done in the context of recommended global TB strategies and targets endorsed by WHO's Member States and broader development goals set by the United Nations.

- ▶▶ For the period 2016–2035, these are WHO’s End TB Strategy and the United Nations’ (UN) Sustainable Development Goals (SDGs), which share a common aim: to end the global TB epidemic.

### Pretomanid -Background of the New Drug:

- ▶▶ The anti-tuberculosis drug pretomanid was recently approved by the U.S. Food and Drug Administration (FDA).
  - ▶▶ It will be a game changer for treating people with extensively drug-resistant TB (XDR-TB) and those who do not tolerate or respond to now available multidrug-resistant TB (MDR-TB) drugs.
  - ▶▶ That pretomanid is only the third drug in the last 40 years to get FDA approval highlights the scarcity of new drugs to treat TB bacteria that are rapidly developing resistance against most available drugs.
1. **Simpler regime** – The all-oral, three-drug regimen of bedaquiline, pretomanid, and linezolid (BPaL) had a 90% cure rate in a phase III trial in South Africa involving 109 participants.
  2. **High success rate** – It had a 90% cure rate in a phase III trial in South Africa; against the current treatment success rate for XDR-TB and MDR-TB at 34% and 55%, respectively.
  3. **HIV** – It was found to be safe and effective in curing TB in people living with HIV.
  4. **Shorter duration** – Unlike 18-24 months needed to treat highly-resistant TB using nearly 20 drugs, the BPaL regimen took just six months.
  5. **Effective and better tolerated** – It was better tolerated and more potent in clearing the bacteria. The shorter duration is more likely to increase adherence to therapy and improve treatment outcomes.

### Pricing of the New Drug:

- ▶▶ The availability of a potent drug is welcome news, it remains to be seen if it would be made affordable, particularly in the developing countries where the burden of XDR-TB and MDR-TB is the highest.
- ▶▶ TB Alliance, a New York-based international NGO, which developed and tested the drug, has already signed an exclusive licensing agreement with a generic-drug manufacturer for high-income markets.
- ▶▶ Unlike in the case of bedaquiline, where its prohibitive cost has severely restricted access especially in the developing countries, pretomanid might become affordable.
- ▶▶ In line with the TB Alliance’s commitment to affordability and sustainable access, the drug will be licensed to multiple manufacturers in about 140 low- and middle-income countries, including India.

- ▶▶ Making the drug affordable to those with extreme form of drug resistance will be highly commendable and a desperately needed model to be followed.
- ▶▶ There is a compulsion to keep the prices low and increase treatment uptake to stop the spread of highly drug-resistant TB bacteria.
- ▶▶ Studies have shown an increase in the number of new patients who are directly infected with drug-resistant bacteria.

### **MDR Burden:**

- ▶▶ According to the World Health Organisation, in 2017, there were an estimated 4.5 lakh people across the world with MDR-TB, of which India accounted for 24%, and about 37,500 with XDR-TB.
- ▶▶ With only a low percentage of MDR-TB cases being treated,] the actual number of people who do not tolerate or respond to available MDR-TB drugs and so will be eligible to receive the BPaL regimen is unknown.
- ▶▶ Though the total number of people who will require the new drug may not be high, these are people who have very little alternative treatment options that are safe and efficacious.
- ▶▶ Also, the number of those who would need a Pretomanid-based regimen is increasing due to rising drug resistance.

### **State of TB in India:**

- ▶▶ The government has committed to achieve a '90-90-90 target' by 2035 (90% reductions in incidence, mortality and catastrophic health expenditures due to TB).
- ▶▶ This is premised on improved diagnostics, shorter treatment courses, a better vaccine and comprehensive preventive strategies.
- ▶▶ However, much work remains to improve case notifications as only 1.9 million TB cases in the public and private sectors were notified in 2016, leaving a 25% gap between incidence and notification, the largest in the world.
- ▶▶ Though notification was made mandatory in 2012, multiple surveys and surveillance data still show large under-reporting of detected TB cases, especially in the private sector.
- ▶▶ Top-line drugs are still inadequate to treat people who suffer from the drug-resistant forms of the disease.
- ▶▶ The number of estimated multi-drug-resistant TB cases increased marginally to 84,000. But the number of people with MDR-TB enrolled for treatment improved marginally between 2015 and 2016.
- ▶▶ For the first time, steps have been taken to offer preventive TB treatment to a small (5%) number of people who are HIV-positive, and 1.9% of children below five years who are household contacts of people recently diagnosed with pulmonary TB.

- ▶▶ Notably, domestic funding (74%) for anti-TB work has been more than that from international sources (26%). The surveillance systems remain inadequate.

### Steps to reduce TB Burden:

- ▶▶ The targets set in the “End TB strategy” are global reduction of 20% in incidence and 35% in mortality by 2020, taking 2015 as the base year.
- ▶▶ To reach that target, the global drop in incidence has to be 4-5% a year — currently it is about 2% a year.
- ▶▶ The percentage of deaths should come down from the current 16% to 10%.
- ▶▶ With India accounting for the highest TB incidence (23%) and mortality (26%) globally, success in realising the End TB targets hinges largely on the country strengthening its systems. The major step in defeating the disease and achieving the targets is to record every diagnosed patient through case notification. When a person is diagnosed with TB, it is reported to the national surveillance system, and then on to the WHO. While better funding might help India inch closer to its stated goal of ending TB by 2025, much more is needed in terms of funding and commitment on all fronts.

### Way Forward:

- ▶▶ It is important to address the social conditions and factors which contribute to and increase vulnerability to tuberculosis.
- ▶▶ Concerted efforts should be made to address the issues of undernourishment, diabetes, alcohol and tobacco use.
- ▶▶ Private sector engagement in combating TB needs to be strengthened. The private sector should also be incentivised to report TB cases.
- ▶▶ There is an urgent need for cost-effective point-of-care devices that can be deployed for TB diagnosis in different settings across India.
- ▶▶ It is important to invest more in R&D to come up with new drug regimens for responding to the spread of drug-resistant strains.
- ▶▶ Further, there is an urgent need to research on an effective vaccine to prevent TB in adults. The India TB Research and Development Corporation must play a pivotal role in accelerating the efforts. Service delivery should be optimised so that the diagnostics and drugs reach to people who need them the most.
- ▶▶ Mass awareness campaigns like ‘TB Harega Desh Jeetega’ can play an important role in breaking social taboos regarding TB and awaring people about the disease, precautions and its cure. Coordinated efforts of all stakeholders is required otherwise the ambitious 2025 target to eradicate TB cannot be achieved.

Source: The Hindu