Combination therapy for TB

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Context: Pre-grant patent opposition has been filed at the Indian Patent office in Kolkata against a French pharmaceutical giant's application for patents of drugs to prevent TB.

- It is a communicable disease caused by **bacteria Mycobacterium tuberculosis** that most often affect the lungs and sometimes also affects other organs.
- Isoniazid and rifampicin are two of the most powerful first line drugs for TB.
- Isoniazid was approved and was available in market in 1952, while rifapentine in 1998.
- Cost of it remains too high for the huge latent TB population in India.
- A standard TB preventive therapy involves isoniazid regimen for six months or more. In June 2019, the World Health Organisation also updated its guidelines to include the regimen for preventive therapy.
- The pharmaceutical, Sanofi, had applied for the patent in 2016 on a combination of rifapentine and isoniazid formulation for adults. Newer studies have shown a combination of isoniazid and rifapentine to be more effective – with lesser liver toxicity and a much shorter treatment duration of three months.
- Granting patents on these combinations could limit the regimen's availability and affordability by blocking access to generic competition

TB

- WHO data shows one-fourth of the population is infected by latent TB bacteria. In 2017, around 1.6 million people died due to the infectious disease.
- Drug Resistant TB:

    - Multidrug Resistance TB (MDR): It is TB that does not respond to at least isoniazid and rifampicin
    - Extensively drug-resistant tuberculosis (XDR-TB): It involves MDR-TB, in addition to resistance to any of the fluoroquinolones such as levofloxacin or moxifloxacin and to at least one of the three injectable second-line drugs
    - Totally drug-resistant tuberculosis (TDR-TB): TB which is resistant to all the first- and second-line TB drugs.
- India, that holds the largest TB burden globally, has an estimated 40 per cent of its population infected by latent TB.
- People living with HIV are twenty times more likely to get TB infection than the normal population. Preventive therapy for such patients becomes important.
- India has set the target of 2025 to end TB epidemic. The India TB Report, 2019, states the country has TB incidence of 27 lakh, but in 2018 only 21.5 lakh cases could be notified.
- Indian programmes against TB
    - Covered in Universal Immunization Programme
    - Mission Indradhanush
    - Revised National TB Control Programme (RNTCP)
    - National Strategic Plan to end TB in India by 2025
- **Other actions**

- Moscow Declaration to End TB
- WHO- End TB Strategy
    - 95% reduction in the number of TB deaths compared to 2015.
    - 90% reduction in TB incidence rate compared to 2015.
    - Zero the level of catastrophic costs