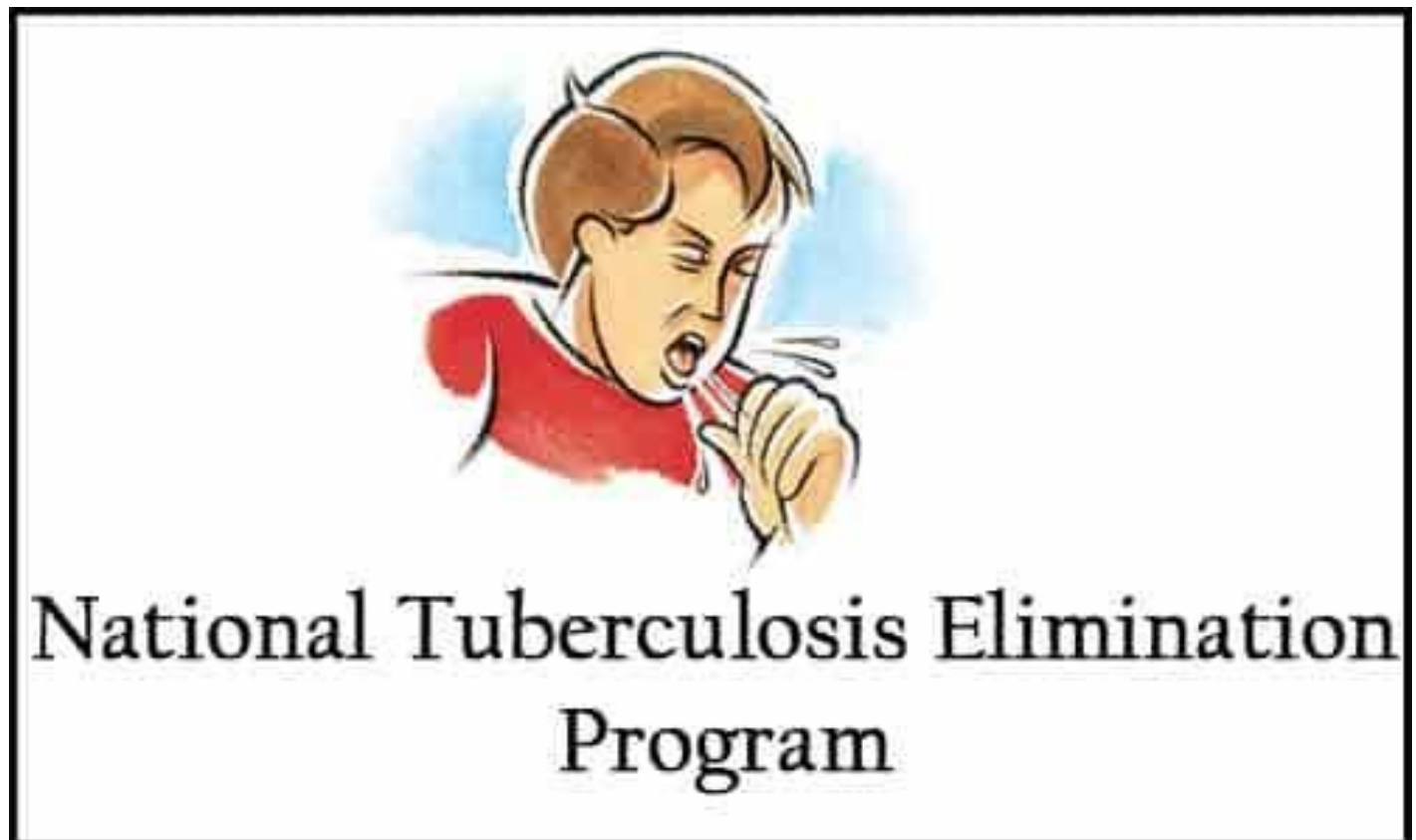


Bedaquiline: India's anti-Tuberculosis fight, and a patent battle

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Why in News?

- Recently, the Indian Patent Office rejected an application by US-based pharmaceutical giant **Johnson & Johnson** (J&J) to extend its patent on the drug bedaquiline beyond July 2023.
- Bedaquiline is a drug in tablet form used to treat drug-resistant tuberculosis (TB).

About Tuberculosis (TB)

- Tuberculosis (TB) is a **bacterial infection** spread through inhaling tiny droplets from the coughs or sneezes of an infected person.
- It mainly affects the **lungs**, but it can affect any part of the body, including the tummy (abdomen), glands, bones and nervous system.
- TB is a potentially serious condition, but ***it can be cured if it's treated with the right antibiotics.***

About Antimicrobial Resistance (AMR)

- Antimicrobials – including antibiotics, antivirals, antifungals and antiparasitic – are medicines used to prevent and treat infections in humans, animals and plants.
- ***Antimicrobial Resistance (AMR) occurs when bacteria, viruses, fungi and parasites change over time and no longer respond to medicines*** making infections harder to treat and increasing the risk of disease spread, severe illness and death.
- As a result of drug resistance, ***antibiotics and other antimicrobial medicines become ineffective and infections become increasingly difficult or impossible to treat.***

Drug-resistant TB

- As of 2017, ***India accounted for around one-fourth of the world's burden of multi-drug-resistant (MDR) TB and of extensively-drug-resistant (XDR) TB.***
 - MDR TB resists treatment by at least isoniazid and rifampicin, the two frontline drugs in TB treatment.
 - XDR TB resists these two drugs as well as fluoroquinolones and any second-line injectable drug.
- XDR TB is rarer than MDR TB – There were 1,24,000 cases of MDR TB in India (2021) versus 2,650 cases of XDR TB (2019).
- TB incidence in India has been on the decline, but MDR TB and XDR TB endanger initiatives to locally eradicate the disease.

How is Drug-resistant TB Treated?

TB can be treated by strictly adhering to the doses and frequencies of drugs prescribed by a physician.
Deviations from this schedule can lead the bacteria to become drug-resistant.

Yet they happen because the drugs often have side effects that diminish the quality of life and/or because patients haven't been afforded access to the requisite drugs on time.

Drug-resistant TB is harder to treat. One important option for those diagnosed with pulmonary MDR TB is **Bedaquiline**.

About Bedaquiline

- Bedaquiline, sold under the brand name **Sirturo**, is a medication used to treat active tuberculosis.
- Unlike second-line treatment options that are injected and can have severe side effects, like permanent hearing loss, **bedaquiline is available as tablets and is less harmful**.
- Studies until 2018 found that it may be toxic to the heart and the liver. This is part of why **it is recommended only when other treatment options for MDR TB have failed**.

News Summary

- Indian Patent Office rejected an application by US-based pharmaceutical giant Johnson & Johnson (J&J) to extend its patent on the drug bedaquiline beyond July 2023.
- J&J's patent application was for the production of a fumarate salt of a compound, with which to make bedaquiline tablets.
- Groups opposing the extension of patent by J&J argued that **J&J's method to produce a "solid pharmaceutical composition" of bedaquiline is "obvious, known in the art" and doesn't require an "inventive step"**.
- According to the **Indian Patent Act 1970**, an 'inventive step' is an invention that is "not obvious to a person skilled in the art".
- They also objected that J&J's application didn't contain information about foreign patent applications, their specifications, and priority dates, among other details, required under the Act. The Indian Patent Office rejected J&J's application on these and other grounds.

What is the Significance of This Measure?

- India has the largest population of people living with drug-resistant TB.
- J&J's patent on bedaquiline meant the drug cost \$400 (Rs 33,000) for the six-month schedule, in addition to the cost of other drugs (revised in 2020 to \$340).
- The **rejection is expected to lower the cost of bedaquiline by up to 80%**.
- So far, the Indian government has directly procured the drug and distributed it through state-level TB programmes.

- Since 2016, India has also availed bedaquiline donated at no cost by J&J and the U.S. Agency for International Development.

Tuberculosis in India

- The total number of incident TB patients (new and relapse) notified during 2021 in India were 19.33 lakh as opposed to that of 16.28 lakh in 2020.
 - India's **National TB Elimination Programme** is strengthened to ***meet the goal of ending the TB epidemic by 2025 from the country***, five years ahead of the Sustainable Development Goals (SDG) for 2030.
 - The **National Strategic Plan for Tuberculosis Elimination** (2017-2025) was developed to achieve the goal.
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Q1) What is a Superbug?

Superbugs are strains of bacteria that are resistant to several types of antibiotics. Each year these drug-resistant bacteria infect more than 2 million people nationwide and kill at least 23,000, according to the U.S. Centres for Disease Control and Prevention (CDC).

Q2) What is Allopathy with example?

Allopathy is a system in which medical doctors and other healthcare professionals (such as nurses, pharmacists, and therapists) treat symptoms and diseases using drugs, radiation, or surgery. Also called biomedicine, conventional medicine, mainstream medicine, orthodox medicine, and Western medicine.

Source: [Explained | Bedaquiline, India's anti-tuberculosis fight, and a patent battle](#)

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