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#### **DISEASE BURDEN**

In 2021, an estimated 10.6 million people fell ill with TB worldwide, of which 450 000 incident cases of rifampicin-resistant or multidrug-resistant TB. About 1.5 million people die from TB each year. Most of the people who fall ill with TB live in LMICs.



## INTELLECTUAL PROPERTY LANDSCAPE

Primary patents on sudapyridine are present in key countries of manufacture such as India, China and South Africa and are expected to expire in 2035. Secondary patents covering manufacturing processes and intermediates with an expected expiry date in 2037 are present in a few LMICs.



### **SERVICE DELIVERY ENABLERS**

**CLINICAL RELEVANCE** 

Sudapyridine is a bedaquiline analogue

and it is not approved yet. Its safety and

efficacy data are still not mature.

Sudapyridine is being developed as an oral drug. Its companion drugs are not known yet but, because of its chemical properties, it is likely to be developed as an alternative to bedaquiline in bedaquiline-containing regimens. Companion drugs may include existing TB medicines, most of which are available as generics, although some are not widely accessible.





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## REGULATORY

Sudapyridine has not yet been approved by any regulatory authority and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.



## **MANUFACTURING**

There is limited data at this stage to assess manufacturing complexity.

### **MARKET**

This medicine is still in the R&D pipeline and therefore little is known about its potential positioning in treatment protocols, pricing, and overall access plans.



