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Finding cures for neglected tropical diseases

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The lack of appreciable market that attracts the investment of research based pharmaceutical enterprises is the reason for lack of development of new drugs for a number of tropical diseases. The challenging question is how to lead the development of new therapies for the diseases that do not attract private investment. The impact of these diseases is substantial on the affected population. Due to the high mortality rates and the large number of persons affected, particularly in the most vulnerable sections of the society, these diseases need priority attention from a governmental and public policy perspective. The following three diseases are just illustrative examples and India is affected by most of these diseases.

Tuberculosis (TB) is one of the leading cause of deaths due to infectious diseases. TB kills someone somewhere in the world every 25 seconds. About 1000 persons die each day in India, two deaths occur every three minutes. Most of these deaths happen in the less endowed neighbourhoods in the tropical region. The current drugs for TB hail from the middle of 20th century and drug resistance has emerged as a major concern.

Malaria is one of the planet's deadliest diseases and one of the leading causes of sickness and death in the developing world. In the south-east Asian region, the highest number of estimated malaria cases was reported in India followed by Indonesia, Myanmar and Bangladesh.

Leishmaniasis or Kala-azar is another poverty-related disease. An estimated 2 million new cases occur annually, with about 12 million people currently infected. Since the introduction of miltefosine at the beginning of the last century, no new anti-leishmanial compounds have been approved for human treatment. India alone shares almost 50 percent of the world's burden of disease. In North Bihar, with world's highest prevalence of disease, traditional treatment with pentavalent antimony injections are becoming less effective.

The list of such diseases is long. But the underlying lack of new drugs remains a common threat that afflicts all diseases that predominantly affect the tropical region, away from the lucrative pharmaceutical markets.

Drug discovery and development is a costly, time-consuming endeavour. The industry estimates drug development cost to be in the range of $800 million or more. The global market of TB is estimated to be between $300-400 million. With malaria, the market is a couple of hundred million. From the industry perspective, R&D costs are very high, and the market is not substantial to support the level of revenues needed to recapture expenses before patent expiry. Thus the industry is not getting competitively engaged. Among the tropical diseases, TB and malaria are the ones which have relatively higher market share. If these cannot attract industry investment, other tropical diseases have much lesser chance.

An associated problem is the lack of adequate scientific understanding of these diseases. In the absence of industry interest there has not been much focus into the study of these diseases. There has been philanthropic support in the recent years. The National Institute of Health of the US has also been funding for such research. Yet, all agree that much more need be done. These diseases should be funded as priority areas of research. Unless the scientific understanding of the diseases is improved the chances of getting better drugs will remain grim. National laboratories in disease endemic countries have a prime responsibility to work on these problems.

Need for public sector investments

As the patients are poor, it is critical that drugs for these diseases are affordable. This can be achieved only if public sector invests in costly and risky clinical trials. Clinical trials take substantial part of the cost. If clinical trial cost is met by public sector, the R&D costs will not figure in the pricing calculation, making drugs affordable. The net effect is essentially to lower the cost and the risk to the company that finally takes on the commercial production and manufacture of the drug. The generic drug industry business model serves as a good example of how the drugs can be made affordable if the R&D costs are removed from the manufacturing costs. It is therefore imperative that public sector should invest in the clinical trials of tropical infectious diseases.

There are three main product development partnerships which focus on these diseases: TB Alliance, Medicines for Malaria Venture (MMV) and Drugs for Neglected Diseases Initiative (DNDi) (working on Leishmania, chagas disease and many more). Philanthropic and institutional funding has been their mainstay. But the problem at hand is much more than these organizations can handle alone. They require active support of the governments of the disease endemic regions to get the drugs in their pipeline approved by the regulators after clinical trials.

Of particular importance is to create clinical trial facilities in disease endemic regions. If such facility is not available, the drugs cannot be tested on the populations for regulatory clearance. Here again, the public sector has to play a lead role in setting up of facilities and then letting them operate. The tropical infectious diseases that affect mostly the poor are essentially a public health problem. Health is a public sector responsibility. Where the market fails to operate, there is no alternative but for the public sector to step in with its resources. Unless governments in the disease endemic regions play a proactive role with investments and support the R&D, these disease will continue to debilitate their population.