A MARKET-DRIVEN VALUE-BASED ADVANCE COMMITMENT (MVAC)

Bringing to market an affordable cure for TB by Crowding in private investment

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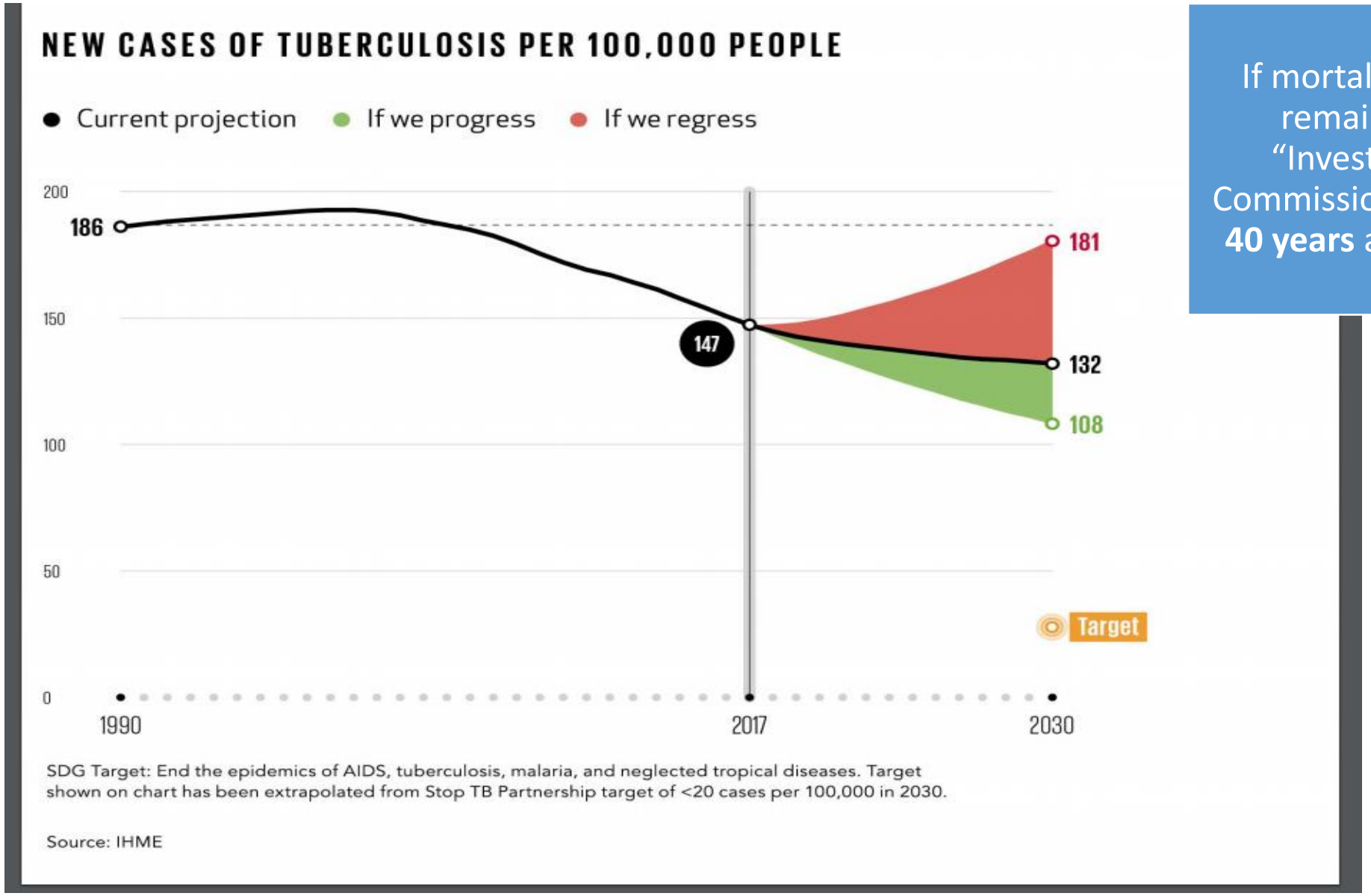
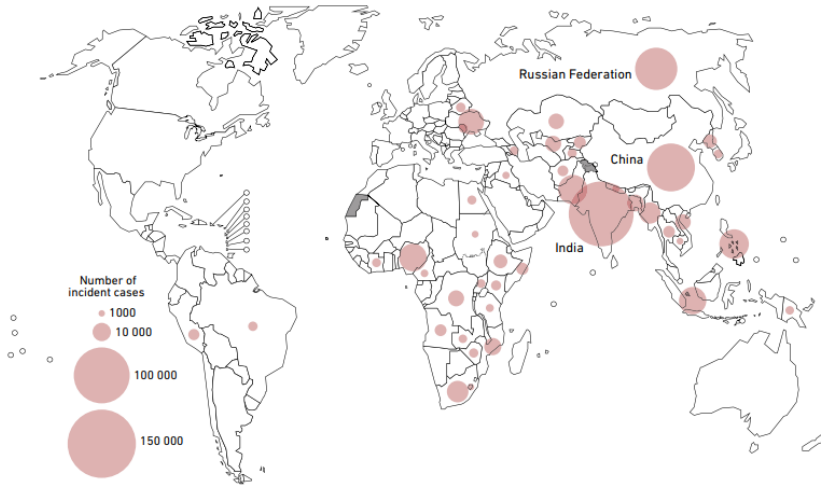


If mortality reduction trajectory remains as per 2010-2016, "Investing in Health" Lancet Commission targets will be reached **40 years** after 2035 convergence*

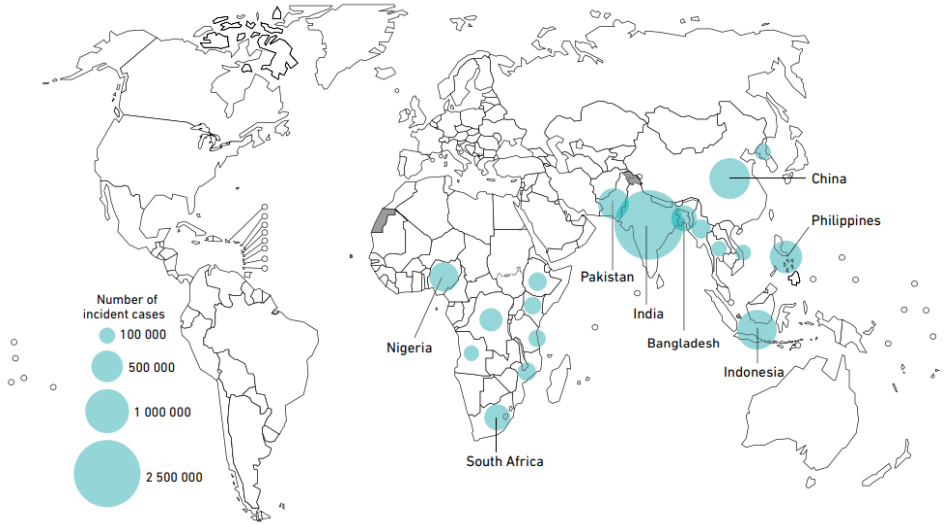
source

FIG. 3.22

Estimated incidence of MDR/RR-TB in 2017, for countries with at least 1000 incident cases

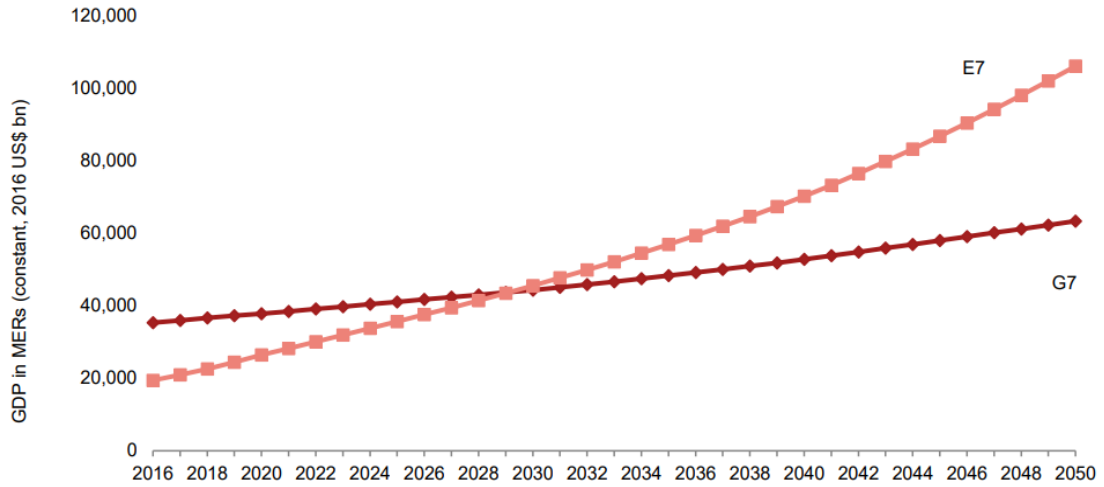


Estimated TB incidence in 2017, for countries with at least 100 000 incident cases



THE MOTIVATION

Figure 7: Growth paths of the E7 and G7 economies in MER terms



Source: PwC analusis

THE MOTIVATION

If mortality reduction trajectory remains as per 2010-2016, investing in health Lancet commission targets will be reached **40 years** after 2035 convergence*

StopTB estimates that $2-2.5 billion is needed between 2016-2020 to drive technological innovation. Only 1/3 of this is committed and 2/3 of that is public.

Private investment dropping ($87 million in 2015 out of £170 billion of private R&D investment – 0.05% of global R&D)

Public investment (BMGF, NIH, HIC donors) makes up bulk of limited TB investment.

Majority of TB patients live in fast growing aid transitioning countries with a growing NCD burden.

* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32389-4/fulltext
https://www.dropbox.com/s/cwji5v10sf9u2hi/TheLifePrize_BusinessPlan%20Dec%202017.pdf?dl=0

Center for Global Development

FOUR CORE ELEMENTS

Health Technology Assessment:
To estimate the **size of the market** including potential price and volumes for the TB universal regimen target product profile (TPP) (using assumptions on TPP effectiveness, projected burden of disease, and a comparator) which will be translated into commitments and implementation/success payments

Under-writing:
To **securitize and monetize a commitment** from MICs for a new TB regimen, accounting for scientific, commercial, and multi-market entry risks. Further, design the size and structure of the reward based on expected return on investment.

Governance:
To develop a governance model which coordinates BRICS and donors, establishing **credibility with countries in driving seat and broad stakeholder/CSO engagement.** Model will include ex-ante and ex-post, supply-side and demand side arrangements.

Industrial Policy:
To ensure **alignment with industrial policy** objectives of MICs, including local TB manufacturing capacity and requirements.

ELEMENT 1: HEALTH TECHNOLOGY ASSESSMENT

- *What?* Reaching, together with buyers/countries and sellers/companies, a common understanding of the value proposition of a new product through the application of globally accepted methods and process principles.
- *How?* Measuring the value that the new treatment would add in each country and then use this value as a benchmark to define price.
  - What is value – given forecast epidemiological profile, compared to alternative (predicted) treatment options, hospitalisation costs and savings, health and productivity gains…
  - What is the ability to pay for that health gain in the context of each particular health system and its budgetary constraints.
- *When?*
  - *ex ante,* pre-launch modelling to predict value;
  - *ex ante,* at launch modelling to assess performance against TPP and value;
  - *ex post,* post launch impact assessment and outcome verification.
- *With…*Leverage existing (emerging and established) national HTA structures in BRICS currently supported through BMGF and DFID (www.idsihealth.org)

INDIA

Message from the Hon. Minister of State (MoHFW)

I/315-3/69/2018
स्वास्थ्य एवं परिवार कल्याण राज्य मंत्री
भारत सरकार
MINISTER OF STATE FOR
HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

अनुप्रिया पटेल
Anupriya Patel

MESSAGE

Health Technology Assessment (HTA) is a form of policy research that examines short- and long-term consequences of the application of a health-care technology. Prime objective of HTA is to ensure value for money to the patients, efficient utilization of the resources and ensure that the actual benefit of innovations reaches to the patients. HTA can solve numerous medical queries and problems for example cardiovascular problems can be resolved by various techniques like reduction of stress at workplace, cessation of smoking or heart by-pass surgeries.

Recognizing the importance of HTA in health services design, management, and delivery of health system, the Government of India has established the Health Technology Assessment in India (HTAIN) with a view to providing the maximum utilization of health care benefits to people.

Our achievements in various fields like **life expectancy, infant & maternal mortality rate, accessibility of healthcare services in rural areas, intensive health campaigns, sanitation devices and increase in number of Government & private hospitals etc** are significant. Improvement in immunization coverage and literacy rate, have improved the overall health of the country. But, the factors like, less health insurance coverage, large number of population lying in the low income group and High bills of medical care for long term disease are of great concern. The majority of healthcare spending in India, is out of pocket (OOP) (82.2%), 74.7% of which is spent on medicines. Many patients in India have been forced below the poverty line due to healthcare expenditure. Set against this backdrop, only 3 – 5% of Indians are covered under any form of health insurance.

I am confident that HTAIN will be a transparent, effective and systematic and unbiased system, which will be able to accelerate the process of providing access to new research and development to the patients and lead to 100% utilization of existing resources.

(Anupriya Patel)

SOUTH AFRICA

"Standards of care, evidence-based treatment protocols and processes for conducting [HTA] to assess the impact, efficacy and costs of medical technology, medicines and devices relative to clinical outcomes must be developed. Findings... should be published to **stimulate competition** in the market, to **mitigate information asymmetry**, and to **inform decisions about strategic purchasing by the public and private sectors**."

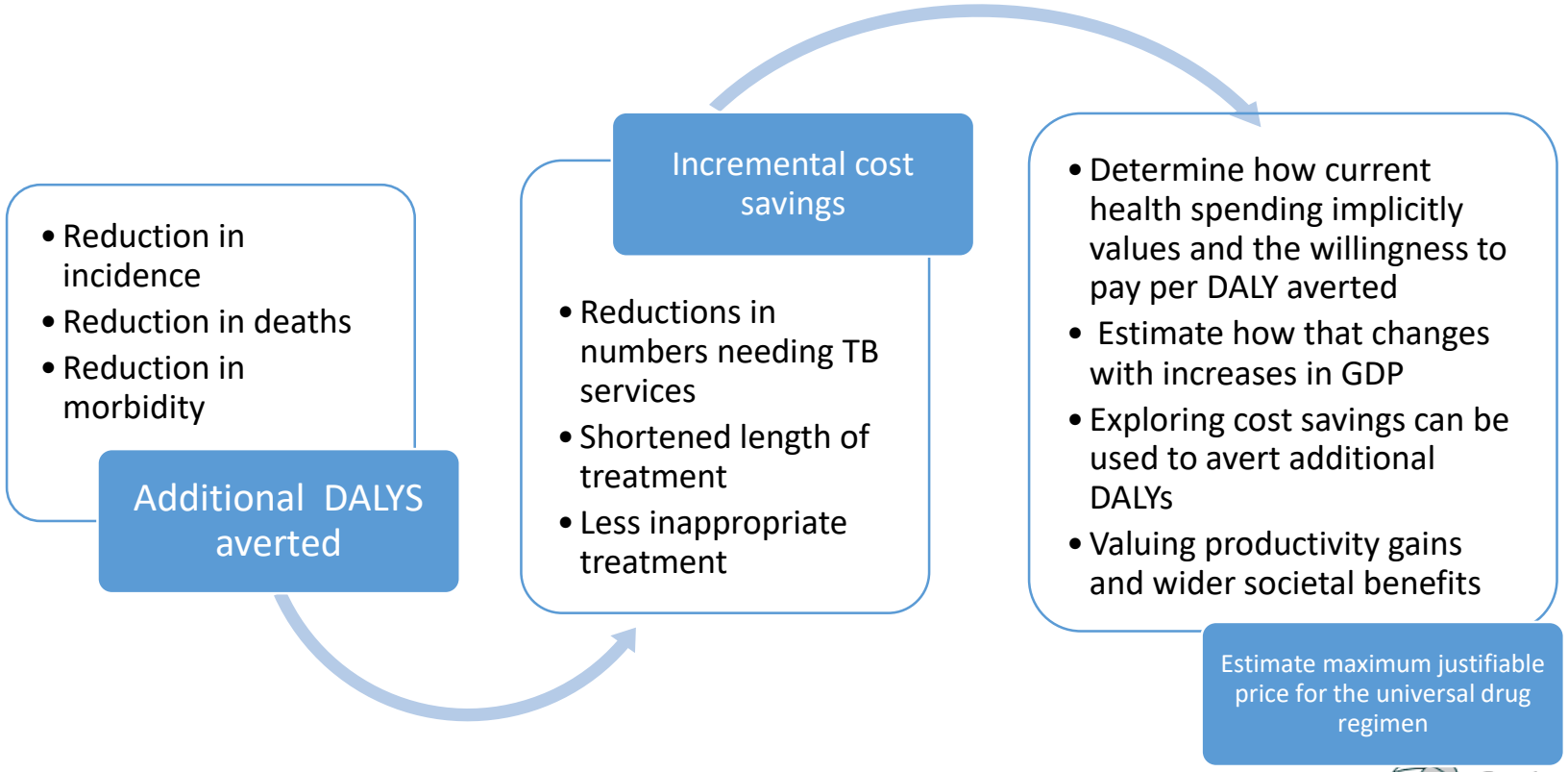
Key attributes of the TPP (WHO, BMGF, industry)

- Universal drug regimen (UDR)
- 2 month treatment
- No drug sensitivity testing
- No pre-existing resistance

NOTES

- A min fraction of the TPP triggers the MVAC – additional performance rewarded in accordance to added value to the max TPP price
- Max TPP price less than max model based value price to account for push incentives/public R&D investment
- Post MVAC IP maintained by firms but product available at cost-plus for MVAC countries and all LICs (from outset)
- Account for techs in pipeline (vaccines, short regimens) as comparators

STRUCTURE OF THE HTA MODEL: VALUING THE REDUCTION IN TB INCIDENCE



ELEMENT 2:
UNDERWRITING TO SOLVE MARKET FAILURE

Key Question:

How can BRICS today make credible commitment to purchase innovative TB drugs at a value-based price…15 years in the future?

Proposed Answer:

By leveraging their own sovereign credit-worthiness, intermediated through a development bank

ELEMENT 3: GOVERNANCE

- Need a global secretariat for international cooperation to assume collaborative minimum governance responsibilities
  - Aggregate and secure demand across countries
    - Manage/coordinate HTA (value assessment) and ex ante pricing negotiations across countries
  - Set parameters of target product profile
  - Expert group to certify whether (and to what extent) new product has met minimum TPP
    - In parallel: coordinate with regulators to fast-track regulatory approval of a new product that has met TPP terms (facilitate partnership with HTA teams)
  - Track fulfilment of commitments

- Specs for appropriate global secretariat
  - Be open and credible to BRICS other emerging markets
  - Show relevance to/expertise in tuberculosis
  - Minimize transaction costs (without compromising programmatic quality)

THE KEY BENEFITS OF THE MVAC APPROACH

1. The Commitment: Structure
   - Made by country governments/payers, based on local priorities and needs assessments – NOT donors. **BRICS-led and BRICS-owned**
   - Secured/guaranteed by development bank as intermediary
2. The Commitment: Value
   - Value-based assessment (HTA)—conducted separately, in each country—as starting point to establish maximum justifiable prices/volumes based on health gains and health systems savings
   - Adjust downwards to account for public money
3. **Credible for Private Sector Investment and Transactionally simple**

Thank you

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