

#### **MVAC:**

## A Proposal to Finance New Life-Saving Drugs for Middle-Income Countries

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# For millions of people around the world, life-saving drugs are within reach but simply aren't being developed, or aren't accessible, because the economic incentives aren't there.

Too often, research and development for new drugs is focused on lucrative high-income markets, neglecting diseases of the world's poor.

One disease where this problem is particularly acute is tuberculosis. Tuberculosis is largely concentrated in middle-income countries and ranks among the top 10 global causes of death—yet treatments remain inadequate due to long and toxic treatment cycles paired with rising drug resistance. In fact, according to a new Lancet study, the Sustainable Development Goal of ending tuberculosis by 2030 cannot be achieved without a major technological breakthrough.

While early-stage "push" funding has helped source new and promising compounds, major new investments are still needed to "pull" these drugs to market. For example, one breakthrough to treat tuberculosis could be a short-course universal drug regimen (UDR)—a single, less toxic treatment that can tackle both drugsensitive and drug-resistant tuberculosis. However, pharmaceutical companies tend to focus their research and development efforts on lucrative high-income markets—generally shying away from investing in innovative products for middle income markets that they perceive as relatively "risky" sources of revenue and profit.

In the absence of an innovative solution, pharmaceutical companies will not invest the needed financial resources to fund larger (late stage) clinical trials required to bring a pathbreaking universal drug regimen to market, and there will simply be no viable path to ending the tuberculosis epidemic in the next decades.

### What is MVAC (market-driven value-based advance commitment)?

The MVAC is a new mechanism designed to mobilize private sector funding for neglected diseases while ensuring broad access to innovative products at an affordable price. The MVAC provides economic incentives for pharmaceutical companies to address global epidemics that disproportionately affect middle-income countries—the emerging economic power centers that are home to 73 percent of the world's poor. Multilateral development banks will underwrite a commitment from middle-income countries to purchase a pathbreaking new product, providing pharmaceutical companies with an incentive to invest in the R&D needed to bring the product to market.

In other words, the MVAC is a new version of the advance market commitment that is driven by middle-income country demand, informed by countries' ability to pay, and allows pharmaceutical companies to enter new markets at locally affordable but still profitable prices. The initial pilot for the MVAC was designed for tuberculosis, but the model could be applied to other disease areas as well.



#### How does MVAC work?

- Evaluate the potential of the new lifesaving drug: Health Technology Assessment (HTA)—a process endorsed by the WHO, well established in some middle-income countries (MICs), including Brazil, and supported by emerging institutions in China, India, Indonesia, and South Africa—will be used to assess the value proposition of an innovative TB therapy. HTAs evaluate the value of a new product through the application of globally accepted methods which review the "medical, economic, organisational, social, and ethical issues related to the use of a health technology in a systematic manner." The MVAC will use HTA-based on country-specific evidence that calculates the value that a new technology would bring to a specific health system and, in turn, different countries' ability to pay for that technology—to inform countries' purchase commitments.
- **Sign a commitment guarantee**: Commitment guarantees—underwritten by a financial intermediary such as the World Bank and/or the Asian Development Bank—will ensure that MICs credibly signal their demand to industry, helping drive R&D investment.

- Align the arrangement with countries' industrial policies: Developing local industry (including homegrown research capacity and pharmaceutical industries) is a priority for many MICs. The flexible MVAC design will align with local industrial policy—for example by partnering with local manufacturers or clinical trial networks.
- Create a governance structure that works for all stakeholders: An MVAC governance structure credible to both MICs payers and industry is required to drive and operationalize the MVAC. This requires it to be authoritative, open, and sufficiently flexible to place MIC governments in the driving seat. Given these requirements, we have initially recommended a World Bank Trust Fund as the best fit for the MVAC's operational needs.

## What exactly are countries committing to pay for an effective drug?

Based on a drug meeting the minimum or optimal results—paired with some conservative assumptions about GDP growth and entry of other new technologies—countries would make locally affordable floor and ceiling total revenue commitments for the new drug in advance of market entry. Within that range, the final price and volume would be calculated via a predefined process and using the HTA model, based on the drug's effectiveness and other pre-agreed parameters that influence its value to country health systems.

#### What can the MVAC do for pharmaceutical manufacturers?

The MVAC offers an opportunity for industry—including both multinational and domestic manufacturers—to engage in and expand a profitable market for TB therapies. The MVAC offers pharmaceutical companies a total guaranteed revenue that varies only within a pre-set range. By providing companies a strong and reliable signal of MICs' willingness to pay for health innovation, the MVAC yields a safe opportunity to develop an innovative treatment for TB that will expand the industry's footprint to less traditional markets. Through the MVAC's guarantee model, new drug development is de-risked, with the innovator company retaining its intellectual property rights in the new drug, protected from compulsory licensing. Domestic industry would compete against multinationals to achieve the MVAC target product profile; a successful multinational company would also leverage domestic industry for manufacturing and distribution.

Over time, the MVAC will enable companies to establish the relationships, experience, and precedent with value-based pricing that would help to expand development for and sales in emerging markets. This expansion will boost both market share and company revenues.

There are reputational benefits for pharmaceutical companies as well: the MVAC enhances a company's corporate social responsibility profile by improving access to medicines in underserved markets.

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