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## **New Report Reveals that R&D Partnerships Serving Neglected Communities Have Produced Dozens of Life-Saving Innovations Since 2010**

*Novel approach for minimizing investment risks and stretching limited budgets has 375 innovations targeting infectious diseases under development*

SILVER SPRING, Md. (January 28, 2021)—The public-private initiatives that contributed to COVID-19 vaccine and drug development have showcased a model for accelerating biomedical innovation. However, public-private partnerships had emerged as powerhouses for fighting global health threats long before the pandemic hit. Over the last decade, such alliances have produced a wide assortment of life-saving technologies targeting diseases that afflict billions in low-income countries, according to a [new report](#) from the International Partnership for Microbicides (IPM) and 11 other PDPs that assesses their impact and future potential.

The report finds that, since 2010, these 12 PDPs have developed and brought to market 66 new drugs, vaccines, diagnostics and other technologies for a number of diseases—including HIV, tuberculosis, malaria, meningitis and sleeping sickness. These innovations have reached and benefitted more than 2.4 billion people in low-income countries. On limited budgets, PDPs build alliances between public, private, academic and philanthropic partners, enabling the sharing of financial risks and coordination of diverse expertise and experience.

IPM’s dapivirine vaginal ring for HIV prevention is one of the successes showcased in the report. The monthly ring could help fill an important gap with the first long-acting HIV prevention option. In January 2021, the World Health Organization [recommended](#) the product as an additional prevention choice for women at substantial risk of HIV infection, following a July 2020 [positive scientific opinion](#) from the European Medicines Agency under Article 58.

“The dapivirine ring is poised to become a new woman-controlled HIV prevention choice—and this was only possible through the expertise, support and dedication of many partners across sectors and countries,” said Dr. Zeda F. Rosenberg, founding chief executive officer of IPM. “PDPs play a pivotal role in addressing health inequities by advancing innovations that would not otherwise exist. This report shows that investments in PDPs are paying off.”

The report notes the stark contrast between the neglected disease product development space before and after the ascent of PDPs around the turn of the century. For example, from 1975 to 2000, a mere 16 of some 1400 newly developed medicines targeted diseases that mainly affected least-developed countries.<sup>1</sup> Since their inception, PDPs have marshalled industry, government and philanthropic investments and generated new political capital to pack a once-barren global health R&D pipeline. Currently, the cumulative pipeline of the PDPs behind the report contains more than 375 new innovations, 25% of them now in late-stage development. That is three times the size of the 2010 pipeline, which itself was many times larger than it was at the turn of the century.<sup>2</sup>

“It’s an unfortunate, but obvious reality, that relying solely on market incentives to drive medical innovation results in neglect of the needs of large portions of the world,” said Willo Brock, Senior Vice

President of External Affairs for TB Alliance, one of the PDPs behind the report. “PDPs have made tremendous advances in global health and our best is yet to come with so many new innovations in late stages of development, but we must stay focused on securing the support we need—from all of our partners—to ensure we build on the momentum of the last decade and realize the promise of our pipelines.”

Alongside the [dapivirine ring](#), additional examples of innovation delivered by PDPs since 2010 include:

- A new drug from **TB Alliance**, pretomanid, for highly drug-resistant forms of TB is the **first treatment regimen approved** for extensively drug-resistant TB—the deadliest form of the disease. Pretomanid is to be used as part of a three-drug, six-month, all-oral regimen.
- A drug developed by **Medicines for Malaria Venture (MMV)** in partnership with GlaxoSmithKline (GSK) called tafenoquine that **requires only a single dose** to prevent relapse of *P. vivax* malaria. This species of malaria is particularly debilitating since it can lie dormant in the liver and relapse multiple times causing new episodes of disease in the absence of a mosquito bite.
- A new medication, fexinidazole, from the **Drugs for Neglected Diseases initiative (DNDi)** that provides the **first all-oral cure for sleeping sickness**, a disease that is usually fatal without treatment. Before the development of fexinidazole, the only treatment available was complicated to distribute and administer in communities of rural Africa where outbreaks still occur, often prompting the use of a toxic medication that killed one in 20 patients.
- An **affordable oral cholera vaccine** from the **International Vaccine Institute (IVI)** to combat a disease that kills 100,000 people every year and sickens 2.5 million.
- The first meningitis vaccine developed specifically for Africa. Known as MenAfriVac, the heat-stable, low-cost vaccine from **PATH** was introduced in 2010. By 2019, mass immunization of 340 million people had **virtually eliminated the deadly disease** wherever it was used across Africa’s “meningitis belt.”
- Bed nets from the **International Vector Control Consortium (IVCC)**, Interceptor® G2, that can **protect against insecticide-resistant mosquitoes** that carry malaria, addressing a major threat to one of the most critical tools for fighting the disease.
- A new drug, moxidectin, that could **accelerate elimination of onchocerciasis** (also known as river blindness). The non-profit biotech PDP **Medicines Development for Global Health (MDGH)** achieved approval in the U.S. as its sole sponsor.

Meanwhile, the current PDP pipeline includes a number of promising innovations. For example, the **International AIDS Vaccine Initiative (IAVI)** is developing broadly neutralizing antibodies against HIV that are infusing new promise into **the quest for an HIV vaccine**. PDPs, including the **Tuberculosis Vaccine Initiative (TBVI)**, have reinvigorated the TB vaccine pipeline, having contributed to the development of **13 of the 20 candidates currently under development**, seven of which are in late-stage development. In 2000, there was no TB vaccine in any stage of development.

The **European Vaccine Institute (EVI)** is supporting the development of a **vaccine against a chronic form of leishmaniasis** that causes debilitating and disfiguring lesions on the face, limbs and trunk for some 100 million people annually in poor communities across 100 countries. The **Foundation for Innovative New Diagnostics (FIND)** and DNDi are part of an effort to develop a **self-administered test for hepatitis C**.

The report finds that a key factor in the success of the PDPs is that they are developing products that are both affordable and easy to administer—like heat-stable innovations versus those with significant refrigeration needs. It also reveals that PDPs are cost-effective. For example, DNDi estimated their cost to develop and bring fexinidazole to market at US \$70-225 million, compared to the \$1.3 billion estimated by the Tufts Center for Study of Drug Development as the average cost for for-profit pharmaceutical developers to develop a novel chemical entity.<sup>2</sup>

### **Tapping PDPs to Fight COVID-19**

Meanwhile, the report documents how PDPs have helped build global capacity to conduct cutting-edge medical research, including working with 550 clinical trial sites in some 80 mostly low-income countries. It notes that this global infrastructure has been tapped to speed the development of COVID-19 vaccines and treatments, and that PDPs have contributed in many other ways to fighting the pandemic. For example:

- IVI has supported the development of COVID-19 vaccines, including work to prepare clinical sites in four African and Asian countries to potentially participate in Phase 3 efficacy trials.
- EVI is also participating in the development of COVID-19 vaccines via its work with the TRANSVAC initiative, which offers free scientific, technical and other services to accelerate the development of urgently needed vaccines for global health.
- IAVI has contributed its considerable expertise in developing broadly neutralizing antibodies against HIV to a collaboration that has identified two monoclonal antibodies with the potential to protect against SARS-CoV2. They will soon advance to clinical trials.
- DNDi and MMV dispatched Pandemic Response Boxes free of charge to researchers in low-income countries, which included 400 compounds active against bacteria, viruses, or fungi, allowing them to be tested for potential use in the COVID-19 response. MMV then launched the COVID Box of 160 compounds with known or predicted activity against SARS-CoV-2.
- FIND is co-leading the Diagnostics Pillar of the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration to ensure equitable access to the tests, treatments and vaccines needed to defeat the pandemic.

The report cautions that in order to continue this impressive track record, the future success of PDPs will require a strong focus on late-stage research and efforts to ensure access to recently launched technologies, given the rapidly maturing pipeline of new products. For example, the report points out that there is a need to ensure funding for research, manufacturing and distribution as well as training health service providers. The report concludes that “with more products approaching and reaching the market than ever before, the need to invest in research and access is increasingly critical and urgent.”

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**For additional information** and to read case studies from each of the 12 PDPs, please visit [www.KeepingThePromiseReport.org](http://www.KeepingThePromiseReport.org).

**About IPM:** IPM is a nonprofit organization dedicated to developing new HIV prevention tools like the dapivirine ring and other sexual and reproductive health technologies for women, and making them available in developing countries. IPM has offices in the United States, South Africa and Belgium. Please visit [www.IPMglobal.org](http://www.IPMglobal.org).

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<sup>1</sup> Grace C. Product Development Partnerships (PDPs): Lessons from PDPs established to develop new health technologies for neglected diseases. DFID Human Development Resource Centre. June 2, 2010. [https://www.heart-resources.org/wp-content/uploads/2012/09/276502\\_UK-Report-on-Wider-Applicability-of-Product-Development-Partnerships-\\_PDPs\\_\\_Report1.pdf](https://www.heart-resources.org/wp-content/uploads/2012/09/276502_UK-Report-on-Wider-Applicability-of-Product-Development-Partnerships-_PDPs__Report1.pdf)

<sup>2</sup> DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics*, vol 47, 20–33, May 2016. <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub>