

May 12th, 2021

The third module of the PSE in Health webinar series was the first of two parts that explore private-public partnership modalities to enable **equitable access** to innovative and affordable health technologies in low-income settings. Part I examined **how collaboration between public-interest organisations and the pharmaceutical industries can strengthen research and development (R&D) of health products that address specific needs of low-income populations.**

<u>Summary</u>

This session focused on the **Product Development Partnership (PDP)** model. PDP is a **non-profit** organisational structure that enables public, private, academic and philanthropic actors to develop drugs, vaccines, and other health products as **public goods**, usually targeting neglected diseases with little to no commercial incentives and that disproportionally affect people in low and middle income countries (LMICs).

Representatives from the Drugs for Neglected Diseases *initiative* (DND*i*), Innovative Consortium Vector Control (IVVC) and Foundation for Innovative New Diagnostics (FIND) illustrated how entering in full partnerships with industry actors enabled them to develop **new and innovative medical products**.

Complementary expertise and resources is at the core of such partnerships. Each party covers the right segment of the value chain based on their strengths, thereby optimising the chances that the products under development will reach those in need. For example, Sanofi and Syngenta shared their compound libraries, R&D platforms and expertise for the development of, respectively, Fexinidazole®, a drug against the sleeping sickness, and Actellic®, a new generation of Indoor Residual Spray (IRS) insecticides for vector control in the fight against malaria. Meanwhile, DNDi's network and infrastructure, which are close to the target patients, made clinical trials of Fexinidazole® possible and IVCC provided laboratories to test and develop Actellic® with resistant mosquito strains. The importance of complementary private-public partnerships was further emphasized by representatives of the pharmaceutical companies Merck and Novartis, who highlighted the different types of collaborations they engage in from discovery to clinical access. With a weak coverage of R&D ecosystem in LMICs, PDPs allows them innovate in areas they would otherwise not explore.

Most importantly, guest experts showcased the comprehensiveness of the role of PDPs. Beyond just bridging the R&D funding gap, partnerships with the private sector cover the entire market chain of new products. As such, they ensure that new drugs, vaccines and health tools appropriately address an existing need, target the right population, and that these products are effectively taken up through targeted market shaping interventions. For example, IVCC made sure to introduce alternative products in the IRS market to rotate with Actellic® and prevent the development of resistant mosquitos. FIND played a crucial role in the development of affordable COVID-19 rapid antigen diagnostics tests and their delivery at point-of-care within the ACT-Accelerator framework. Matching private actors across the value chain led to a significant reduction of diagnostics test costs and they ensured access to these products by building-up local

manufacturing capacity in LMICs, coordinated negotiations and pooled procurement, and provided regulatory process support and policy guidance.

Considering the whole scope, i.e. from R&D, delivery and all the way to access, is crucial to developing new effective health technologies. However, this requires a continuous, dynamic and transparent negotiation and planning process, embodied in a Target Product Profile (TPP). TPPs are technical documents that describe the target population, the interventions that are required and the minimal intervention characteristics. The best products include the "3As, 1Q formula" in their R&D and marketing framework:

- Access: do we have the right R&D framework? Are we pushing towards the right target? Once we have a product, can it be delivered in a specific setting? Is the targeted health system able to set up a suitable supply chain for this product, such that it can be delivered to the right place at the right time?
- Acceptability: Is it the right formulation? Will it operate in a low-resource setting (e.g. outside of a cold chain)? Do the drugs have side-effects and can we remove them? Will the patients accept to use this product?
- Affordability: Is the price right?
- Quality of the product: lower prices should not compromise the product quality and effectiveness

In an effort to increase the efficiency of these efforts, the Special Programme for Research and Training in Tropical Disease, hosted by the WHO, has developed the <u>Health Product Profile Directory</u>, which provides guidance on priority needs in medical product R&D for neglected diseases and populations, as well as threats to global health. In identifying priorities, specifying minimum characteristics and translating them into technical language for R&D actors, TDR seeks to make an investment case for the development of products with low commercial incentives.

Take-home messages

- 1. Given the long process of development and marketing of new health products, PDPs rely on **long-term collaborations** with **selected** partners.
- 2. Partnerships are built around **complementary** of strengths, competencies and expertise.
- 3. The **incentives for private R&D actors** to enter such partnerships are additional R&D funds and developing markets that would have otherwise remain untapped.
- 4. The PDP model goes beyond just closing the R&D funding gap.
- 5. PDPs take an **end-to-end perspective of access** to medical products, from discovery to delivery.
- 6. Equitable access to medical products does not solely depend on affordable prices.
- 7. PDP engagement requires **careful planning at the very outset of R&D** to ensure appropriate interventions that **guarantee accessibility**, **acceptability**, **affordability and quality**.
- 8. Setting the right price of a new product is the result of a **long**, **transparent and honest negotiation process** that follows the product development pathway.