

Snapshot

Background and challenge

Poverty related neglected diseases (PRND) such as tuberculosis, malaria, and HIV affect predominantly the world's poorest countries where there is limited health care infrastructure, a lack of universal insurance schemes as well as low economic power of patients to pay for necessary medical treatment. As a result, there has been little financial incentive for the global pharmaceutical industry to invest in research and development (R&D) to develop effective medical products that improve the health situation of people in lower and middle income countries (LMIC).

Format

Since the late 1990s, Product Development Partnerships (PDPs) have been set up with the objective to develop and to improve access to new products for people who suffer from diseases and health threats and are underserved by the market. PDPs initiate, strengthen and coordinate multi-stakeholder partnerships between the public, private, academic and social sectors. PDPs work with different partners across all stages of product development, from discovery to market access. Funding for PDPs comes either from governments, development agencies or philanthropic donors. PDPs also benefit from inkind contributions from academic, and research institutions as well as the pharmaceutical industry. The latter are encouraged and incentivized to contribute with their unique know-how and other resources

The Swiss government has been an early supporter and funder of several product development partnerships (PDPs). These include the Foundation for Innovative New Diagnostics (FIND), the Medicines for Malaria Ventures (MMV), and the Drugs for Neglected Diseases initiative (DNDi). Switzerland has become a hub of health research, product and development benefitting from proximity to international organisations such as the World Health Organisation (WHO), health NGOs, excellent research infrastructure, leading pharmaceutical companies as well as a strong philanthropy sector.

Benefits/Results

The main benefit of PDPs is that they can bring to life many health innovations benefiting people in developing countries that would not be developed if left to the pharmaceutical industry or governments alone. PDPs furthermore ensure that products reach as many end beneficiaries as possible and are tailored to specific needs, preferences, and affordability. PDPs have considerable cost advantages over private or public actors developing their own products and they strengthen local health systems.

Recent evaluations show that the PDP model has indeed been a game changer to PRND related medical innovation. Selected PDPs assessed within the context of a major review in 2020 have collectively mobilized almost USD 5 billion (2007–2018), brought 85 new products to market and currently have more than 300 products in the R&D pipeline. The PDP model of collaborative medical innovation also helped enable a rapid and effective global response to COVID-19.

Outlook

PDPs now have an important role to play in shaping the global health R&D system for equitable access to health products and technologies in LMIC and beyond. Important issues that influence the future of PDPs are an increased focus on access consideration in the product lifecycle, new funding models, synergies between PDPs, enhanced coordination in the global health R&D system, the influence of technology and digitalisation of processes, and data collection for costing.

1. Context

This case is about Product Development Partnerships (PDPs). PDPs illustrate the increasing importance of public engagement with the private sector and the power of multi-stakeholder partnerships for sustainable development in international development cooperation:

► Private sector engagement

According to a growing consensus in international development cooperation, the private sector has a critical role to play to help achieve the goals set out in the 2030 Agenda for Sustainable Development. Partnering with private companies has enabled development agencies and governments around the world to benefit from private actors' know-how, innovation power, networks, finance, and other resources. More recently, development agencies have been diversifying and strengthening partnerships with other types of private sector organizations: philanthropic grant-makers to

co-fund social innovations and mobilize private capital for impact, financial institutions and impact investors to complement scarce development finance resources as well as support organizations for Social and Impact Enterprises (SIEs) and start-ups to leverage new ideas and entrepreneurial solutions for critical development challenges.

Multi-stakeholder partnerships

The UN recognises that a single actor will not have the resources and expertise required to adequately address the big societal challenges the world is facing, including access to reliable health care. As a result, the UN Sustainable Development Goals call for multi-stakeholder partnerships such as PDPs that mobilise and share knowledge, expertise, technology, and financial resources to tackle complex challenges together.

2. Challenge

According to the World Health Organisation, more than one billion people suffer from one of the so-called poverty-related neglected diseases (PRND), such as African sleeping sickness, malaria, tuberculosis or HIV/AIDS. These diseases disproportionately impact the most disadvantaged regions and populations in the world, resulting in tremendous morbidity and mortality. They severely burden ill-equipped health systems that cost developing economies and donors a significant percentage of the available health budget.

Investment into research and development (R&D) of new medical products and treatments by the health industry for these diseases that can be used under the special conditions in developing countries remained stagnant for decades. This is because pharmaceutical companies have been reluctant to launch large R&D projects on PRNDs in low- and middle-income countries as such projects are typically perceived to be less profitable and riskier. Indeed, few people in developing countries have the economic power to buy effective treatments, social security and health insurance hardly exist, and government spending on public health care and infrastructure is limited.

Development agencies are unable to fill this gap in the health sector alone. Increasing experience of development agencies working with private sector partners and in multi-stakeholder partnerships facilitated the creation of PDPs as a response to these challenges. Since the late 1990s, more than 20 PDPs have emerged and successfully demonstrated that such partnerships — if effectively designed and implemented - can help address some of the shortcomings of the commercial pharmaceutical R&D system.

The PDP Coalition is a network of 12 leading PDPs. It includes the Medicines for Malaria Ventures (MMV), the Drugs for Neglected Diseases initiative (DNDi) and the Foundation for Innovative New Diagnostics (FIND), all supported by the Swiss government.

3. Format

Objectives

The PDP model has been created with the intention to overcome a significant market failure for PRNDs. PDPs aim at developing more, less costly, and better-quality medical products – i. e. drugs, vaccines, diagnostics, vector controls, and treatments – compared to what the market would provide for these kinds of diseases. PDPs also seek to strengthen local capacities in LMIC and to improve access in order to scale health impact.

Institutional set up

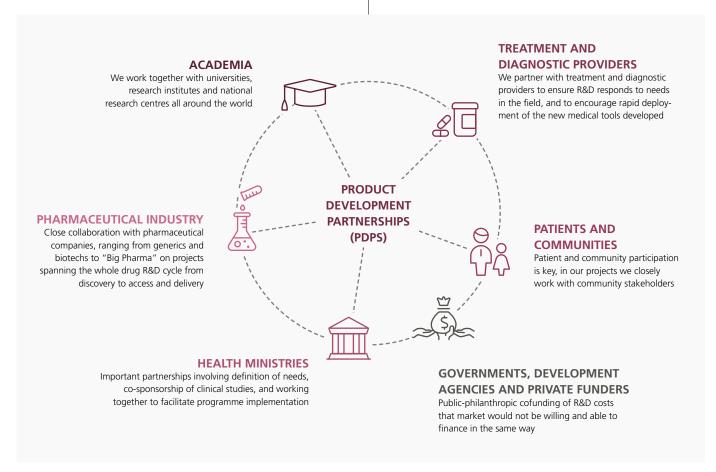
PDPs are non-profit organizations that are each devoted to a specific disease or set of diseases. The donor community and governments pool their resources into a PDP for the development of a specific medical product. Funds for PDPs come in most cases from governments, development agencies or philanthropic donors. PDPs

also benefit from in-kind contributions from industry partners as well as academic and research institutions.

The PDPs use pooled resources to select the most promising projects and manage them through the product development process. As partners are critical to the success of any PDP, they have been set up as 'conductors of a virtual orchestra' or 'platform managers' rather than aiming to provide all activities in-house. They initiate and coordinate partnerships across geographies, sectors and disciplines including, between local communities, non-profits organisations, government agencies, corporates, policy makers, health providers, research institutions, and many other actors (Figure 1).

Figure 1. PDPs as orchestrators of partnerships

Source: based on MMV, DINDi and FIND (2020): Presentation to the Advisory Committee on International Cooperation



PDP's product development pathway

PDPs work across all stages of product development, from discovery to market access partnering ,with a range of different entities at different stages of the process. Effective partnership management therefore plays a critical role throughout the entire product development pathway (Figure 2):

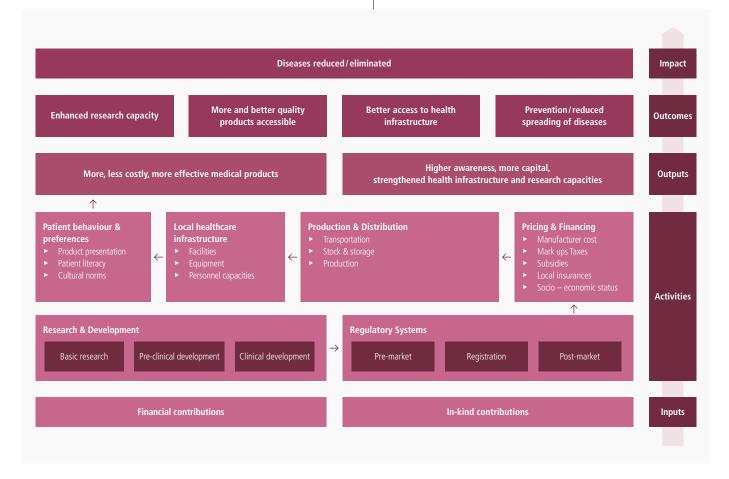
Research and Development (R&D)

Collaborative research and development activities are at the core of PDPs' missions and activities. Some PDPs have their own R&D capabilities and perform research tasks themselves. Most PDPs, however, engage in virtual product development such as that they retain direct management, scientific overview, and strategic oversight of research programs, while much of the laboratory and clinical work is performed through partners, external research facilities, and contractors.

Regulatory Systems

If successful at clinical trial stage, a product is then submitted to the national or regional regulatory authorities to ensure that it meets standards for efficacy, safety, and quality. Collaboration with international, regional, and local regulators and other bodies are needed until the new product is included in the Essential Medicines List that specifies the medications to which people should have access at all times in sufficient amounts at generally affordable prices.

Figure 2. Impact pathway PDPs Source: based on SDC (2018): What drives access to quality medical products for all (flyer)?



Pricing & financing

Only by an agreement on an effective distribution of costs and risks between various stakeholders from the public and private sector, new products can be sold at affordable prices. A new medical product's affordability and thus its accessibility depends for example on the prices set by the manufactures and their wholesalers, the existence of local health insurances and reimbursement schemes offered, as well as the purchasing power of patients and their families.

Production, distribution & healthcare infrastructure

Access to medical products depends on (local) production, storage and transportation capacities in LMIC, as well as factors such as the availability of health facilities, medical equipment, and qualified personnel. As a result, PDPs often cooperate with local (government) institutions, businesses and NGOs that enhance local logistics and health care capacities.

Patients' behaviour

The acceptance of a new medical product by both patients and healthcare providers depends on factors such as cultural norms and beliefs, the product branding and features such as form, dosage, taste or colour. Community based organisations, non-profit partners as well as governments are involved throughout the process given their considerable influence over patient behaviour and acceptance.

Zooming in: Swiss support to MMV, DNDi and FIND

The Swiss government has been an early supporter of PDPs with a total volume that by now reached more than CHF 80 million. With many PDPs headquartered in Switzerland, the country has become a hub of health research and

product development benefitting from proximity to influential international organisations such as the WHO and international health NGOs, excellent health research infrastructure, leading pharmaceutical companies, as well as a strong philanthropy sector. However, PDPs work globally with many international, regional and local partners in LMIC and some have set up local offices across Africa, Asia and Latin America. 1 The Swiss government supported the Medicines for Malaria Ventures (MMV), the Drugs for Neglected Diseases initiative (DNDi), and the Foundation for Innovative New Diagnostics (FIND) as well as several other PDPs.

- ▶ MMV, established in 1999 as one of the first PDPs, aims at discovering, developing, and delivering new effective and affordable antimalarial drugs. It has been set up with seed money by the Swiss, Dutch and British Government, the World Bank, and the Rockefeller Foundation and now receives funding from a wider range of governments, private foundations, corporations, and private individuals. The MMVs total funds received between 1999 and 2021 amounted to around USD 921 million with an annual budget of USD 89.2 million in 2020.2
- ▶ DNDi, established 2003 in a partnership between seven major NGOs, foundations, research bodies, and government agencies in both developing and developed countries, has been set up to develop new drugs or new formulations of existing drugs against neglected communicable diseases such as tuberculosis or sleeping sickness.
- ► FIND, also established in 2003 by a grant by the Bill and Melinda Gates Foundation, aims at spurring diagnostic innovation and make testing an integral part of sustainable, resilient health systems to combat diseases and to improve pandemic preparedness.

FIND, for example, partners with more than 200 academic, industry, governmental, and civil society organisations worldwide. MMV manages an extensive partnership network of around 150 active partners including from the pharmaceutical industry, academia, NGOs, and government agencies of endemic countries. DNDi works with over 200 partners in more than 40 countries. More than 1/3 of collaborating institutions with more than 700 researchers are based in LMIC. Some PDPs have a strong local presence in LMIC. For example, DNDi has 8 regional offices

The largest contribution is made by Bill and Melinda Gates Foundation with around 44% of the total budget, followed by the British Government with 27% of the contribution.

4. Benefits / Results

Benefits of the PDP model

PDPs have several benefits: The main being that they can bring to life many health innovations benefiting people in developing countries that would not be developed if purely left to the market or governments. In addition, PDPs are effective beyond product development: their processes and partnerships ensure that products are brought to markets and thus to the end beneficiaries. Furthermore, PDPs have considerable cost advantages over private or public actors developing their own products. Finally, PDPs contribute to building local capacities and strengthen local health systems in many ways.

Results of the PDP model

Two decades since the first PDPs became operational, the performance has been mostly positive with regard to all of the benefits aimed for when PDPs have first been established.³

Overcome market failure

While the health responses on PRNDs remain inadequate with still only around two percent of the annual health R&D budget spent on PRNDs, evaluations found that PDPs have been "game changers". In fact, ten PDPs assessed within the context of a major review have collectively mobilized a total of almost USD 5 billion between 2007 and 2018, brought 85 new products to market (including three vaccines, 27 therapeutics, 50 diagnostics or health technologies, and five vector control tools) and currently have more than 300 products in the R&D pipeline.

Access and health impact

Achieving impact at scale for PDPs means that suitable medical products are not only developed but also adopted by local health systems and remain affordable and acceptable to end users. While

access bottlenecks continue to exist, considerable progress has been made. The Access to Medicines Foundation (AMF) noted, for example, that:

"PDPs are extremely successful in incentivizing access friendly R&D (...) and ensuring future access is taken into account early in the product development process."⁵

Cost effectiveness

Recent data has provided increasing evidence on PDPs' cost advantages over private or public actors developing products on their own. For example, DNDi estimated the full costs for its research and development of a new chemical entity at USD 70–225 million, while the pharmaceutical industry pegs such costs at USD 1 billion or more. PDPs have also successfully mobilised additional funding for product development to combat PRNDs.⁶ An external evaluation by the Dutch government on the PDP model in 2021 emphasised the value for money of PDPs:

"The PDPs continue to demonstrate good value for money. The PDP model – pooling funds, working in partnerships, taking a portfolio approach – can result in products being developed at a third or less of the cost of private sector development." ⁷

Strengthening local health (R&D) systems

PDPs have successfully strengthened local health systems in many ways: By supporting clinical trials, partnering with local research institutions, enhancing scientific skills through training, improving local research capacities, mobilising communities, engaging policy makers, and supporting local voices in international advocacy efforts. The increasing presence of some PDPs in LMIC demonstrated benefits in both directions – local knowledge improved the product design and access, while local systems have been strengthened and local capacity and expertise has been built.

Recent and relevant evaluations on the PDP model include, for example, Bulc, Ramshandani (2021), Ecorys (2021) and DFAT (2020).

⁴ Bulc, B. Ramchandani, R (2021). P 7.

Bulc, Ramshandani (2021). P 12.

⁶ MMV estimates in its annual report, for example, that the organisation achieves a financial leverage of USD 3.5 i. e. USD 1 of donor funding is matched by USD 3.5 of external funding and in-kind contributions through its partners. MMV (2021).

Australian Department of Foreign Affairs and Trade (2021).

Response to COVID-19

The experience with PDPs' models of collaborative medical innovation accelerated the development of rapid and effective global responses to COVID-19 in low-income countries and resulted in the development of diagnostics, vaccination, and therapy. This included for example, the Access to COVID-19 Tools Accelerator (ACT-A) led by FIND,8 the COVID-19 programme under the Geneva-based Vaccine Alliance Gavi,9 or the COVID-19 Therapeutics Accelerator¹⁰ – all programmes co-funded by the Swiss government. Indeed, PDPs have contributed to identifying COVID-19 variants and developing COVID-19 vaccine candidates and therapeutics by PDPs granting access to their chemical libraries to be tested for efficacy against COVID-19.

Results of MMV, DNDi and FIND

MMV, DNDi and FIND all achieved considerable results in terms of catalyzing innovation, achieving health impact, and strengthening local health systems. For example, FIND developed 24 new diagnostic technologies since 2003, DNDi created five disease specific clinical research platforms in Africa and Latin America, and between 2009 and 2021, MMV-supported products have saved an estimated 2.7 million lives, mainly children below the age of five (Figure 3).¹¹

Figure 3. Overview of MMV, DNDi and FIND achievements (2020/21).

Source: based on MMV, DINDi and FIND (2020): Presentation to the Advisory Committee on International Cooperation

SUSTAINABLE GOALS

CATALYSING INNOVATION

DNDi:

DNDi:

100% of patients diag-

nosed with HAT receive

a DNDi treatment

8

field-adapted and affordable treatments delivered, including fexinidazole, the first oral treatment for sleeping sickness and DNDi's first new chemical entity MMV-

11

MMV:

2009

MMV-supported products

have saved an estimated

2.7 million lives since

new antimalarials developed since 1999, plus two more transferred to MMV from DNDi

FIND:

24

24 new diagnostic technologies developed since 2003

Swiss investment
of over CHF 60 million,
primarily core funding
(outside of COVID-19
activities)



FIND:

Over 55 million FINDsupported diagnostics procured since 2015, over 3,000 labs and sites strengthened

BUILDING RESEARCH CAPACITY AND STIMULATING CRITICAL RESEARCH

DNDi:

- ► Five disease-specific clinical research platforms created in Africa and Latin America
- Over 2,500 patients enrolled in active clinical trials at any given time

MMV:

 Clinical partners in more than 55 countries



FIND:

- ► ISO-certified quality management system for in vitro diagnostic clinical trials
- ➤ 71 clinical trials undertaken with 32,500+ patients enrolled in studies since 2015

- 8 https://www.finddx.org/covid-19/act-accelerator/
- 9 https://www.gavi.org/covid19

IMPACT WHERE IT MATTERS

- https://www.therapeuticsaccelerator.org/
- ¹¹ More information on achievements of MMV are available on https://www.mmv.org/our-impact/milestones; of DNDi on https://dndi.org/diseases/ and of FIND on https://www.finddx.org/impact/.

5. Outlook

The PDP model has been one of the most successful multi-stakeholder partnership approaches in international development cooperation and there are many insights to be gained beyond research and access of new medical products. PDPs now have an important role to play to shape the global health R&D system for equitable access to health products and technologies in LMIC and beyond. Key debates and trends that will shape the future of PDPs include:

Access considerations

An enhanced focus on access and health impact as opposed to R&D will become a strategic consideration from the beginning of a product lifecycle. This can be achieved by providing for deeper collaborations with international pharmaceutical companies, local health providers, and end-users. Furthermore, regional initiatives will increasingly improve product access efforts across PDPs and different PRNDs. This includes, for example, the UNDP-led Access and Delivery Partnership (ADP)¹² and the global initiative Uniting Efforts.¹³

Data assessment and standardisation

The work on data collection, analysis, and standardisation will be further strengthened to ensure broader comparability and transparency on cost effectiveness of new medical products and the PDP model itself. This will ultimately enhance the investment case for PDPs in comparison with traditional standalone R&D processes and allow for a more careful design of incentives for private sector engagement.

Revisiting funding models

The success of PDPs will continue to depend on the ability of PDPs to attract the amount and quality of capital that is required to achieve internationally agreed targets for PNRDs. It has been argued that funding needs to become more predictable, more diverse (including private sector sources), and more flexible across the full value chain.

► International health R&D coordination

COVID-19 has shown the need of cross-sectoral, global collaborations for which the PDP model provides important insights. As a result, the case has been made for an aggregator or global health R&D platform being set up and funded by a broader variety of stakeholders with the aim to develop and implement a global R&D roadmap, to enhance links between global and national efforts, to make prioritisation more effective, and to support both mobilisation and allocation of funding to global R&D priorities.¹⁴

► Tools and technologies

New tools and technologies, in particular artificial intelligence, platform technologies, open source methodologies, or data sharing tools have already or will soon enhance the way in which PDPs, R&D platforms, and other actors in global R&D operate, collaborate, and analyse cost and impact data. This will avoid duplications, increase efficiencies and learning, and remove bottlenecks on Intellectual Property.

¹² https://adphealth.org/

¹³ https://www.unitingeffortsforhealth.org/

¹⁴ Bulc, B. Ramchandani, R. (2021). P 16.

6. Additional Resources

Australian Department of Foreign Affairs and Trade (2021). Product development partnerships fund: mid-term review.

Download here.

Bulc, B. Ramchandani, R. (2021). Accelerating Global Health R&D: The Role of Product Development Partnerships.

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Koenig, A.-N. et al. (2020). Innovative Development Finance Toolbox.

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