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Enabling product development partnerships to bring forward the next generation of health technologies

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Abstract

Over the past quarter century, product development partnerships (PDPs) have importantly brought health technologies, particularly for neglected diseases, to market for low- and middle-income countries (LMICs). With public sector financing, PDPs de-risk the gulf between where the global burden of disease falls and where paying markets exist. From fighting COVID-19 to developing novel antibiotics, the work of PDPs now extends beyond these traditional bounds. As PDPs have shepherded more health technologies to market, they are also confronting new access challenges. This article lays out 5 areas to strategically leverage the PDP model for better access to new health technologies. Making the case for enhanced support of the PDP approach will require greater transparency, as well as recognition of the contributions made by both public and private sector partners. The governance and funding of PDPs must be accountable to meeting the needs and building capacity of target beneficiaries in LMICs. To take an end-to-end approach, PDPs must work in tandem with other public sector institutions as well as local manufacturers as part of a larger innovation ecosystem. PDPs will need to keep pace with both the dynamics of diseases and markets in delivering the next generation of much needed health technologies.

Lay summary

Product development partnerships (PDPs) play an important role in bringing new and needed health technologies to market, particularly in low- and middle-income countries. As these products emerge from the R&D pipeline, new access challenges in paying for and delivering them in the health care system have emerged. The COVID-19 pandemic has also both stretched and tapped into this work. These developments provide a window of opportunity, both to take stock of lessons learned and of strategic opportunities to leverage the PDP model beyond its traditional bounds of neglected diseases. Greater transparency and recognition of the contributions of PDPs, accountability of governance and surety of financing, and coordination with pooled procurement and local manufacturing initiatives can build a foundation for even more impactful contributions in the future.

Key words: product development partnerships; neglected diseases; access; accountability; innovation.

Introduction

Over the past quarter century, product development partnerships (PDPs) have sought to overcome market failures by combining public and private sector resources to bring forward technologies to meet public health needs. Product development partnerships have focused on diseases of poverty, diseases neglected by high-income country markets. In 1994, the Rockefeller Foundation held a Bellagio conference on accelerating research and development (R&D) of a preventative HIV vaccine. The conference recognized the need for a globally coordinated approach that would fill research gaps, recruit needed financial resources, and enlist both public and private sectors to spur forward the vaccine's development. But its vision of a small secretariat, with a finite lifespan and an estimated budget of US$160 million per year, evolved over a quarter century later, into a PDP with over 170 employees, and its work now spans to vaccine candidates for tuberculosis (TB), Marburg virus and Sudan Ebola virus, and COVID-19 as well as HIV/AIDS.[1] By 2004, at least 25 of these PDPs were tackling neglected diseases in low- and middle-income countries (LMICs),[2] and 63 R&D projects were underway.[3] By 2021, at least 66 health technologies emerged from PDPs, reaching an estimated 2.4 billion people over the prior decade.[4] The PDP pipeline includes at least 375 technology candidates.

Product development partnerships build a portfolio of projects around a technology-specific or disease-specific focus. Much of this work is outsourced to a virtual network of partners. From early on, PDPs recognized that partners in the private sector came with different motivations. Half the projects with PDPs in 2004 were with multinational companies carrying out these neglected disease projects on a no-profit, no-loss basis. However, most of the rest were with small-scale firms that found the commercial prospects of working on a neglected disease sufficiently attractive to pursue the opportunity. Small-scale firms also found value in PDPs' technical inputs, from setting up clinical trials to understanding LMIC markets.[3] Corporate social responsibility, reputational gain, co-branding, or the opportunity to open new markets might

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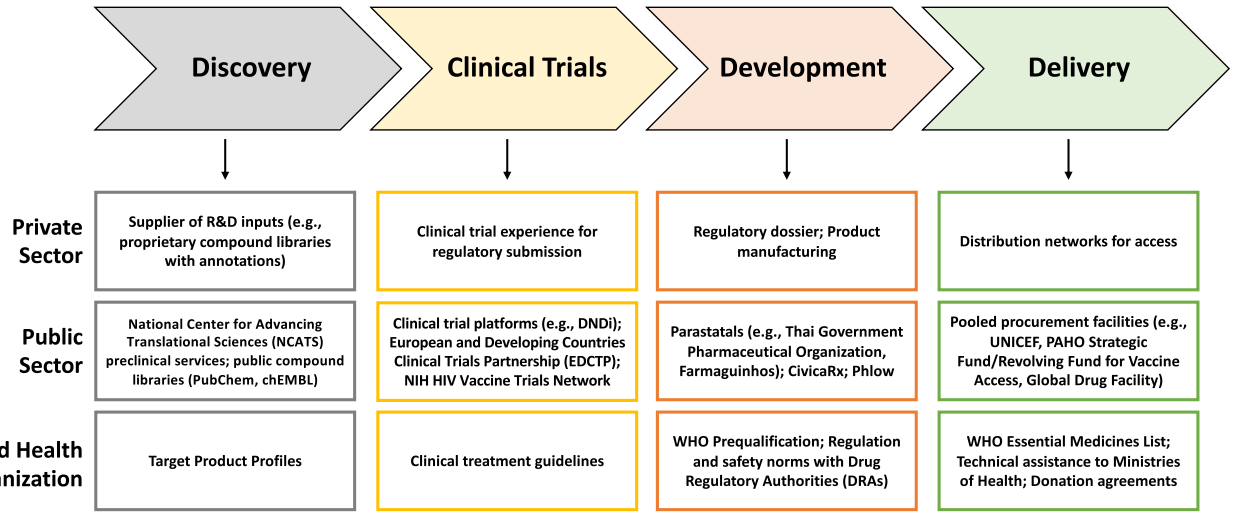

Figure 1. Product development partnership engagement of partners across the value chain. Abbreviations: DNDi, Drugs for Neglected Diseases Initiative; NIH, National Institutes of Health; PAHO, Pan American Health Organization; R&D, research and development; WHO, World Health Organization.

also play a role in a firm's decision to partner. Their successes, to name a couple, include PATH and World Health Organization's (WHO's) Meningitis Vaccine Project, which partnered with the Serum Institute of India to bring Group A meningococcal conjugate vaccine (MenAfriVac) to market at less than $0.50 per dose.[5] The TB Alliance worked to develop pretomanid, just the second US Food and Drug Administration–approved drug for drug-resistant TB.[4]

Coming to market, health technologies have faced barriers of therapeutic, financial, and structural access. By therapeutic access, we refer to whether drug developers undertake R&D for these neglected diseases. Financial access addresses concerns of marketplace affordability to the target populations in need, and structural access, the last-mile challenges of ensuring the effective use of these technologies in the health care delivery system. From bench to bedside, these barriers correspond to different points in the pharmaceutical value chain—respectively, the R&D pipeline, the marketplace, and the health care delivery system. Product development partnerships have particularly focused on the challenge of therapeutic access—that is, whether the drug, diagnostic, vaccine, or medical device for a disease is under development in the R&D pipeline. With public sector support, PDPs are positioned to help bridge product R&D that would not be prioritized in high-income country markets. As more health products developed by PDPs have reached the market, PDPs now must focus more on issues of financial and structural access as well.

This article explores how the PDP model needs to evolve to respond to these latest challenges. We developed 5 areas for strategic leverage by PDPs and their partners to ensure that the PDP model delivers fully on its promise to provide access to new health technologies to billions of people living in poverty in LMICs. First, as PDPs draw upon both public and private sector contributions, transparency is essential to assess the returns on investment. Second, as the main objective of PDPs is to develop and provide access to health technologies addressing neglected diseases in LMICs, access conditions should be an integral part of public financing agreements with PDPs. Third, the governance of PDPs should reflect their main constituency—namely, beneficiaries in LMICs. Fourth, greater coordination and collaboration across PDPs and other pharmaceutical R&D efforts is needed in the complex innovation ecosystem. Finally, PDPs need to contribute to an end-to-end approach that aligns other elements beyond the traditional R&D system, such as local production and procurement, to enhance access to its end products.

Ensuring transparency to assess fair returns on PDPs

As entities that draw upon significant public funding, mixed with private sector contributions, PDPs were launched with the promise of accelerating access to health technologies for neglected diseases endemic to LMICs. Making transparent the contributions of public and private sectors to PDPs not only recognizes and incentivizes such efforts but also clarifies where such investments help to bring such health technology products to market (Figure 1). For instance, drug companies can accelerate PDP progress by providing access to annotated, proprietary compound libraries, sharing experience in running clinical trials for regulatory dossier submission, and advance product access through established distribution networks. Nearly 60% of the compounds screened by the Drugs for Neglected Diseases Initiative (DNDi) from 2012 through 2018 were made freely available by pharmaceutical or academic partners.[6] For its part, the public sector can offer preclinical services, much as the US National Institutes of Health's (NIH's) National Center for Advancing Translational Services (NCATS) does, to address bottlenecks and to help speed drug candidates to first-in-human clinical trials.[7] The European and Developing Countries Clinical Trials Partnership (EDCTP) networks expertise across research institutions in Europe and sub-Saharan Africa to enhance the research capacity and accelerate the clinical trial testing of medical interventions of poverty-related infectious diseases.[8] Government-owned, local production of pharmaceuticals can also play a significant role in bringing health technologies to market. The DNDi worked to develop an antimalarial, fixed-dose combination of artesunate and mefloquine in partnership with Farmanguinhos/Fiocruz, a parastatal pharmaceutical company in Brazil. The partnership

also resulted in a South–South technology transfer of the production process from Farmanguinhos/Fiocruz to Cipla Ltd, an Indian generic drug manufacturer.[9]

By shaping the enabling environment for introducing new health technologies, WHO also contributes valuably to public–private sector collaboration. By developing target product profiles, WHO provides pharmaceutical developers clear signals as to where public health priorities are and how these might be met. Clinical treatment guidelines, as well as updating the WHO Essential Medicines List, can accelerate adoption of a technology or temper its uptake and use. WHO prequalification can pave the way for scale-up and procurement by international procurement agencies. These efforts across WHO might benefit from further strategic coordination.

The story to be told for PDPs is one of convergence between public and private sector contributions, and many PDP partners are smaller firms, including those from LMICs. The PDP annual reports recount more often accomplishments than setbacks or failures. Evaluation reports of PDP progress are seldom made publicly available.

Greater public investment does not guarantee closer-to-marginal cost pricing of the product. In fact, prices in the United States for 20 top-selling drugs were significantly higher than in other countries, such as Canada, Denmark, Ireland, and the United Kingdom, and the magnitude of this difference was not explainable by the global R&D budgets of the companies responsible for bringing them to market.[10] The gulf between the estimated cost of producing a drug and the manufacturer's price also has repeatedly demonstrated that input costs and output price do not track either.[11] Despite the World Health Assembly's call for increased transparency of pharmaceutical R&D costs, this remains an area where such data are seldom released. However, if the public sector pays for such costs, then it should be in a position to make such R&D costs transparent and knowable. This transparency will not only allow comparisons in R&D efficiency and the speed of bringing a technology to those in need but also serve as a benchmark of PDP performance against which to gauge how much health care payers should spend on a technology.

Measuring PDP success along access metrics is also complicated by the breadth of diseases covered and technologies involved. However, more might be done to assess the returns on investment for public health, the capacity building in disease-endemic countries, and the value these efforts bring to private sector partners. The value of in-kind contributions can be challenging to quantify, and contractual arrangements between companies and the PDP may not be publicly transparent. For PDPs, it is important to see how effectively public sector financing leverages private sector contributions and to recognize, if not incentivize, such efforts. Aligning incentives for pharmaceutical innovation to achieve fair pricing is a key measure of accountability for fair returns on public sector investment.[12] However, fair returns for the public sector are not just financial in the form of more affordable pricing of end-products but also in the knowledge generated, technology platforms developed, and clinical trial data disclosed.

Integrating access conditions on public financing of PDPs

To ensure that products for neglected diseases are accessible, PDPs de-risk with public sector financing and resources the gulf between where the global burden of disease falls and where the paying markets exist. As such, PDP products for neglected diseases should reflect access conditions coupled to the significant public financing involved. However, serving such resource-limited markets too often is considered just part of the exceptionalism of neglected diseases rather than a part of fair returns for public support.

Since WHO endorsement in 2010, the Xpert MTB/RIF system has considerably shortened how long it takes to diagnose TB and determine drug resistance to the use of the first-line TB drug rifampicin to a turnaround time of less than a couple hours. The Foundation for Innovative New Diagnostics (FIND), a PDP dedicated to ensuring more equitable access to diagnostics in low-resource settings, played an important role in guiding implementation and up-take of this technology in LMICs. Scaling up this technological breakthrough has required public financing at a capital cost of US$17 000 per GeneXpert 4-module unit and at a rate of US$9.98 per cartridge, but this volume-discounted pricing is primarily for the government and nonprofit health facilities in eligible countries.[13] Cost-of-goods analyses have raised questions whether such investments to improve access to these health technologies for neglected diseases constitute a fair return on public sector investment. In fact, a cost-of-goods analysis estimated the cost to manufacture these cartridges at US$4.64 per cartridge, leading civil society organizations to call on Cepheid, the Xpert MTB/RIF system manufacturer, to lower their price to US$5 per test.[14]

The public sector, as well as FIND, had invested at least US $250 million in the development of this platform and diagnostic assays, but has not been able to secure more affordable pricing arrangements despite meeting the expectations of the initial volume-discounted price back in 2014.[15] Cartridges for other diseases, also used on the GeneXpert platform, have exceeded this price point. Beyond neglected diseases, the Xpert Xpress SARS-CoV-2 diagnostic cartridge came initially to nearly US$20 before the company relented partway to civil society pressure and lowered the price to US $14.90.[16] However, the public sector remains locked into the Cepheid platform and the use of its proprietary cartridges. As a diagnostic technology that might test for a range of diseases, this situation reveals how such decisions by 1 PDP arrangement can anchor future access in other disease areas.

With only certain countries eligible for discounted or tiered prices, this can also result in broader or narrower geographic access, depending on how the tiered arrangement was initially negotiated. The significance of these tiered pricing arrangements, set by companies, has taken on greater significance over time. In 1987, 90% of those living in extreme poverty lived in low-income countries, but by 2013, 60% of those living in extreme poverty resided in middle-income countries.[17] This shift has proved particularly consequential for the Pan American Health Organization's (PAHO's) Revolving Fund for Vaccine Access, where most Latin American countries fall into the low-middle- or upper-middle-income country categories. While the PAHO Revolving Fund requires suppliers to provide PAHO with its lowest available price, vaccine companies may have policies that do not offer preferential prices to middle-income countries. This has proven to be a challenge for the PAHO Revolving Fund in securing pneumococcal vaccines.[18]

Bringing increasingly novel health technologies to market with public financing, PDPs should be positioned differently than private drug companies in striking tiered pricing arrangements. For example, in 2017, the Global Antibiotic Research and Development Partnership (GARDP) had originally

secured commercial rights to zoliflodacin—a promising first-in-class, novel antibiotic to treat uncomplicated gonorrhea—in up to 168 countries, while Entasis Therapeutics had retained rights in the remainder of the global market.[19] Access conditions negotiated by PDPs can anticipate the needs of those living in poverty in middle-income countries.

Enabling effective governance of PDPs

Most PDPs are not housed in government agencies. Moving these partnerships outside the United Nations (UN) system marks a historical evolution over several decades, where public and private sectors have found convergent interests to bring to market diagnostics, treatments, and vaccines to address conditions that might otherwise be neglected by the private sector left to its own devices.[20] As nonprofit organizations, PDPs may have accountability to funders, to public and private sector partners, and to potential beneficiaries in disease-endemic countries. Unlike UN agency programs, there may not be accountability to member states, except where individual countries are bilateral donors to PDPs.

To varying degrees, the moorings of such accountability might be represented in the Board governance of PDPs. Boards have the responsibility to define the mission, shape the vision and approach by which this mission is pursued, and hold fiduciary responsibility. Key strategic decisions made by PDPs reflect the values by which Boards see their responsibilities. Who should then be represented on the Boards of PDPs to ensure effective governance, particularly of public sector and philanthropic investments?

Funders have a significant influence on the direction taken by PDPs. Over the past 5 years alone (2017–2021), PDP funding for neglected diseases amounted to US$2.6 billion. Over 83% of that financing came from just 5 funders (Figure 2 and Table S1). In accepting financing from government or philanthropic funders, certain commitments carry through to PDPs and their partners. For example, funding from the US NIH may come with public access requirements for making available peer-reviewed journal articles resulting from the R&D, data-sharing provisions, IRB (Institutional Review Board) requirements for the study of human subjects, and disclosures acknowledging such funding in patent filings. Major biomedical foundations such as the Wellcome Trust and the Bill and Melinda Gates Foundation have also instituted access policies, both over peer-reviewed publications and inventions generated. Public funding agencies could do more by ensuring what they fund is made available for PDP efforts. The COVID-19 Technology Access Pool (C-TAP) has struck licenses, particularly from publicly funded research agencies such as the US NIH and Spanish National Research Council (CSIC), that follow the principles of global, nonexclusive licensing in the Global Solidarity Call to Action. Recently, the University of California, Berkeley, and Universities Allied for Essential Medicines announced a new affordable access plan for licensing health technologies developed by academic researchers.[21] Efforts to license technologies for broader access in LMICs can also help bolster the work of PDPs.

Examining the 10 top-funded PDPs, the Board composition of these organizations represents a range of perspectives (see Appendix Table S2). Those with pharmaceutical industry backgrounds comprise 17% of Board members, while Board members with industry backgrounds outside of the pharmaceutical industry comprise another 24%. Those with academic backgrounds held 15% of positions and governmental institutions, only 14% of positions. Among these Boards, intergovernmental and private philanthropies held just 5% and 4% of seats, respectively (see Appendix Table S2). Of note, these Boards had few representatives with affiliated institutions in LMICs, where PDP products were typically destined. Fewer than a quarter of all Board members (23%) among the top 10 funded PDPs came from LMICs. In fact, 4 of these top 10 funded PDPs had no more than 1 LMIC Board member (Appendix Table S3).

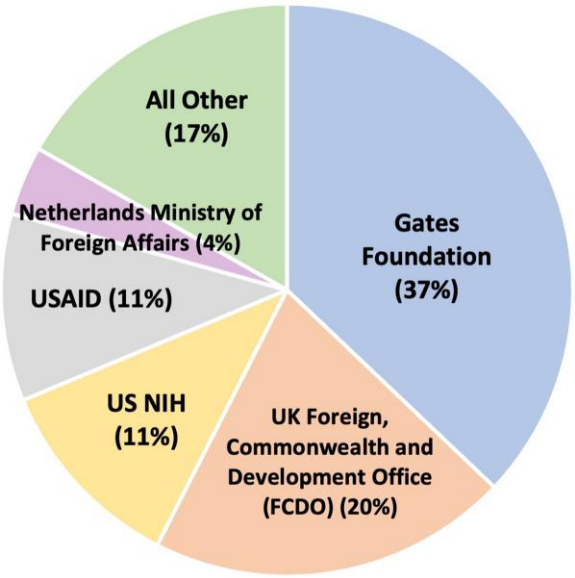

Figure 2. Top 5 product development partnership funders, 2017–2021. Abbreviations: NIH, National Institutes of Health; USAID, United States Agency for International Development. Source: Data from G-FINDER Data Portal, available at: https://gfinder.policycuresresearch.org.

Why is Board composition and governance important? These nonprofit institutions shepherding millions of dollars in public and philanthropic monies make important value decisions. What segmenting of country markets constitutes an acceptable trade-off between access to preferential pricing and protection of commercial interest of a private sector industry partner? What provisions over licensing intellectual property, R&D costs, cost-of-goods analysis, and access conditions warrant commercial confidentiality, and what should be made transparent to better serve the public's interest? What role should PDPs play in supporting an innovation model based on publicly supported open science, and where must those values be conceded to enable a public–private sector collaboration to move forward? Should one take the longer road to bringing a health technology to market if more indigenous capacity is built in disease-endemic countries? What priority is given to local production as opposed to importing the PDP end-products into disease-endemic countries? How are local clinical trial platforms managed and made available for the study of treatments not the focus of the PDP, but still relevant to other locally endemic diseases? These value decisions help shape not just access to the products brought forward by PDPs but also set precedent and parameters to the innovation ecosystem by which future products come to market.

Improving coordination and collaboration in the innovation ecosystem

Today, PDPs sit within a complex innovation ecosystem. The reach of their efforts to develop and deliver health

technologies requires partnership not only across public and private sectors but also among themselves and with new or emerging entities that help shape market access. This became particularly evident as PDPs stepped up to support global efforts to address the COVID-19 pandemic. The case for greater coordination across and among PDPs has never been more compelling.

Among PDPs, some have taken on the mission of sister entities. In 2011, OneWorld Health joined PATH as one of its drug development programs, and in 2018, Aeras' TB vaccine programs were acquired by the International AIDS Vaccine Initiative (IAVI). In 2015, DNDi transferred management of 2 fixed-dose artemisinin combination therapies that it had developed over to another PDP, the Medicines for Malaria Venture (MMV).[22]

Drug-resistant gonorrhea illustrates the complexity of this unfolding landscape. Over 100 million people each year become infected with gonorrhea, a bacterial infection that increasingly has proven resistant to antibiotic treatment. The WHO has ranked gonorrhea resistant to third-generation cephalosporins and fluoroquinolones as a high-priority pathogen[23] and has developed a target product profile for antibacterial agents that might treat drug-resistant gonorrhea.[24] Upon anticipated market entry, GARDP would have the commercial rights to deliver zoliflodacin to most LMICs and a few high-income countries. Access to zoliflodacin, however, will need to be coupled with effective stewardship, and that may depend on the availability of diagnostics for drug-resistant gonorrhea. In its portfolio, CARB-X, a funder of technologies addressing drug-resistant bacteria, has had several rapid diagnostic tests under development and other treatments targeting drug-resistant gonorrhea.[25] Around the same time, the first results of randomized controlled trials for meningococcal OMV (outer membrane vesicle) vaccination for gonorrhea are also expected. This interplay of technology approaches and the range of partners behind them demonstrate the need for strategic coordination on this landscape.

Launched in 2017, the Coalition for Epidemic Preparedness Innovations (CEPI) sought to be a global partnership that would "develop and deploy new vaccines to prevent future epidemics." Together with Gavi, WHO, and other partners, CEPI supported the COVAX Facility to accelerate the development, scale-up, and delivery of vaccines for COVID-19. However, Operation Warp Speed would create a parallel pathway for developing a COVID-19 vaccine, with little attention to ensuring global access, let alone limits on profit-taking. Bilateral deals struck by high-income countries would leave much of the rest of the world at the back of the queue for vaccine doses.[26] The shortcomings of this approach have been widely documented, and the glaring inequity of COVID-19 vaccine distribution a persistent reminder of these failings and the need for improved global coordination.[27]

The COVID-19 pandemic brought out the need for synergy between disease areas and technology platforms that led to concerted efforts by PDPs.[28] The DNDi and MMV stepped up to make available a Pandemic Response Box, composed of 400 druggable molecules, with diverse mechanisms of action against microbes, that could be tested as possible treatments for COVID-19. The FIND supported the WHO Access to COVID-19 Tools (ACT) Accelerator's Diagnostics Pillar, and in addition to CEPI's key role, IAVI and the International Vaccine Institute collaborated with partners working on developing vaccines for SARS-CoV-2. As witnessed in the development of technologies to address drug-resistant gonorrhea, public sector investments have taken divergent paths to bringing forward solutions to market.

Going forward, the shifting burden to noncommunicable diseases will also broaden the potential focus of technologies developed by PDPs. Noncommunicable diseases account for over 7 out of every 10 deaths, or 41 million lives each year, and over three-quarters of those noncommunicable disease deaths are in LMICs.[29] A century after the discovery of insulin, more than 420 million people have diabetes, and only half of the 63 million requiring insulin have access to this life-long therapy.[30] From multiplex diagnostic test platforms to mRNA vaccine technologies, the innovation ecosystem should direct efforts to address noncommunicable diseases as well. In finding dual markets, health technologies otherwise limited to neglected diseases or pandemic periods may be sustainably produced for endemic diseases and in non-pandemic times.

Building an end-to-end approach with procurement and local production

An end-to-end approach is defined by how elements beyond the traditional R&D system can be deployed to help ensure sustainable access to health technologies. The pandemic underscored the importance of system-level interventions, from pooled procurement to local production, to complement PDPs in ensuring access to essential health technologies. Pooled procurement facilities, from UNICEF to PAHO's Revolving Fund for Vaccine Access, have played a critical role in securing and delivering what COVID-19 vaccine doses became available. Their potential role in completing an end-to-end strategy to bringing health technologies from bench to bedside has long been recognized. Pooled procurement refers to collaborative efforts among buyers of a health technology to share market information, coordinate purchases, or even engage in joint purchases. This can result in lower prices as a result of monopsony power, improved efficiency in procurement, and assurances to suppliers of market demand for products. A systematic review of this literature, dating back to the Rockefeller Foundation's work commissioning Management Sciences for Health, reveals a host of reasons for public sector, pharmaceutical pooled procurement. Reduced unit prices, improved selection and quality assurance, lower operational costs and better supply chain management, and lessened corruption in procurement practices were among the reasons described as potential benefits.[31]

The experience of the Global Drug Facility in becoming a 1-stop shop for TB medicines, diagnostics, and supplies also informs how pooled procurement is a key part in managing access to essential medicines. The Global Drug Facility forecasts demand for suppliers to ensure a stable supply for treatments of multidrug-resistant TB infections, and at the same time, negotiates concessionary prices from those manufacturers.[32] To smooth out the disruptions of spot shortages of some TB products, the Global Drug Facility created a strategic rotating stockpile to ensure that those needing the drug now receive it. Pooled procurement facilities represent an important institutional player that can help the public sector more fully engage with the dynamics of the marketplace.

Longstanding supply chain problems for even generic medicines point to gaps that PDPs have yet to fill. The stark inequity of COVID-19 vaccine access has renewed interest in local production of essential medicines and vaccines as a

potential solution path. The promise of local production rests on whether such an approach can build sustainable, local capacity to innovate and manufacture these products; ensure health security at the national or regional level; and importantly, do so at an affordable price. The wide divergence between what manufacturers charge and what it costs to produce medicines also raises questions as to what the optimal mix of public–private sector collaboration is in seeding such efforts. Parastatals like Bio-Manguinhos/Fiocruz and Butantan Institute have long contributed to ensuring a safe and affordable vaccine supply for Brazil and represent exceptional, but important, examples of public sector production. Butantan, for example, produced more than 43 million influenza vaccine doses in 2016—accounting for 88% of total demand in Brazil.[33]

More recently, nonprofit production as an alternative pathway has also emerged. Founded in 2018, CivicaRx is a nonprofit generic drug manufacturer now providing over 50 medicines to 1400 hospitals, comprising nearly one-third of all hospital inpatient capacity within the United States.[34] With no equity holders, the stewardship of this social welfare organization has no shareholders seeking greater returns on their investment. A key operating principle is that those institutions joining Civica receive the same, low contract prices for medicines. Minimum viable volume contracts commit members to buy about half of their expected drug volume from Civica for at least a 5-year period, thereby enabling the assurances of stable demand for contracted suppliers and, to Civica, the lowest prices to deliver sustainably these medicines to its members. The Civica health care utility model offers a private sector, but nonprofit, alternative to public sector production.

Conclusion

Navigating the dynamics of the pharmaceutical market has presented significant challenges to PDPs. Despite some notable successes, the PDP vision of bringing health technologies to those in need faces new challenges, from licensing key technologies to scaling for sustainable success. These developments also have implications for the governance of PDPs, shining a spotlight on where PDPs are headquartered, who sits on their Boards, and how effectively they build capacity in disease-endemic countries, not just whether they deliver affordable medicines. Noncommunicable diseases and COVID-19 have shown the need to grow PDPs beyond meeting the needs of neglected infectious diseases. The innovation ecosystem relies on a complex web of institutions, from WHO's role in shaping the enabling environment and norms for these technologies to come to market to pooled procurement facilities and alternative models for scaling and locally producing these pharmaceutical products. Product development partnerships may need to evolve to keep pace with the changing dynamics of taking on an end-to-end approach to developing and delivering the next generation of much needed health technologies.

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A.D.S., with the help of M.H. and J.W., conceptualized the project, and J.W. collected data for underlying analyses, with guidance and assistance from A.D.S. A.D.S., J.W., and M.H. contributed to the analysis, review, and verification of the data. A.D.S. and J.W. drafted and revised the manuscript, with inputs from M.H. All authors had final responsibility for the decision to submit the final version for publication.

Supplementary material

Supplementary material is available at *Health Affairs Scholar* online.

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Conflicts of interest

Please see ICMJE form(s) for author conflicts of interest. These have been provided as supplementary materials.

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