



Strengthening WHO's role in public health innovation

A PDP perspective

A JOINT INITIATIVE OF



Over recent decades, Product Development Partnerships (PDPs) have advanced a new approach to research and development. PDPs have demonstrated that a needs-driven, not-for-profit, research and development (R&D) model can deliver substantial public health value.

PDPS SINCE 2010

79	700+	98	US\$13	1.6M
health technologies developed and introduced	sites with strengthened research capacity	countries hosting those sites	in health benefits per US\$1 invested (MMV)	deaths averted (MMV)

Several hundred further health technologies continue to advance through PDP pipelines.
Return-on-investment source: Lancet Global Health analysis.

WHO and PDPs: connecting research to access

Neither role can substitute for the other.

WHO PROVIDES
Priorities Evidence-generation standards
Policy guidance
Quality assurance Technical guidelines
Programmatic guidance Country reach

PDPS ASSEMBLE
Scientific partnerships
Clinical partnerships
Manufacturing partnerships
Access partnerships

Reform of global health architecture offers an opportunity to strengthen the World Health Organization’s (WHO) role in enabling innovation that responds to public health needs, particularly those underserved by commercial R&D. Through its priority-setting, scientific guidance, standards, product assessment and policy recommendations, WHO helps connect R&D and the introduction of new health technologies with country needs. Reform should strengthen these connections so that promising innovations can be assessed rigorously and translated more efficiently into public health benefits, in a timely manner.

Collaboration between WHO and PDPs strengthens their respective contributions to the development and introduction of health technologies that address unmet public health needs. Without WHO’s provision of key normative functions, the PDP model would not have been possible. WHO and PDPs perform distinct but interdependent roles. WHO provides priorities, guidance on evidence of generation standards, policy guidance, quality assurance, technical guidelines, programmatic guidance and country reach. PDPs assemble the scientific, clinical, manufacturing, and access partnerships needed to develop and support access to those products where commercial incentives are insufficient. Neither role can substitute for the other.

These are relatively low-investment, high-return functions. A WHO priority, guideline or standard can shape decisions by funders, developers, regulators, procurers and national programmes across many countries at once. This is where WHO’s comparative advantage as a global organization plays a role: setting norms and standards that others can act on, rather than duplicating operational functions that countries and implementing partners can deliver more efficiently.

Global Health Architecture reform should recognise that WHO and PDPs perform distinct but mutually reinforcing functions within the innovation ecosystem. PDPs complement WHO by translating global health priorities into tangible needs-driven R&D outcomes. The PDP experience offers practical lessons for strengthening this role. Priorities need to become actionable research agendas; developers need timely and coherent scientific advice; and product assessment and guideline development need to connect with country planning for introduction. Reform should make these functions more predictable, coordinated and responsive, while safeguarding independent assessment and evidence- based recommendations. The following proposals identify where investment and changes in working practices could improve that contribution.



The asks

- 1 **Recognize the functions of WHO and PDPs explicitly** in the task force's interim report of the Joint Task Force on Global Health Architecture Reform. Designate an empowered and dedicated capacity for cross-PDP relation management and lead point of contact for PDPs at WHO headquarters, with sufficient seniority, an understanding of PDP operating models and a clear mandate to coordinate engagement across relevant departments, linked to designated focal points in relevant regional offices and country offices as needed.
- 2 **Safeguard the specialist expertise and institutional independence** underpinning these WHO functions, including: priority-setting and pipeline analysis; target product profiles; coordinated scientific advice, prequalification and Expert Review Panels; guideline development; the Essential Medicines and Diagnostics Lists; and AWaRe and ethics review.
- 3 **Set, publish and monitor service standards** and indicative timelines for key WHO processes and report on performance. Strengthen WHO's capacity to coordinate product assessment, prequalification and guideline development for innovations addressing major public-health priorities, including poverty-related and neglected diseases, and extend parallel processes where appropriate while maintaining rigorous, independent assessment.
- 4 **Implement the accepted ethics review of reliance recommendations**, with sufficient secretariat capacity, to reduce duplication and delay without weakening ethical standards.
- 5 **Improve the consistency and predictability of Framework of Engagement with Non-State Actors (FENSA) implementation** for engagement with PDPs across departments and all three levels of WHO, relying upon up-to-date organizational information where appropriate and publishing indicative processing timelines, while retaining engagement-specific risk assessment and conflict-of-interest safeguards.
- 6 **Provide predictable, protected financing for these core functions**, rather than relying predominantly on short-term or earmarked funding that can fragment priorities and erode specialist capacity.
- 7 **Strengthen coordination across WHO headquarters, regional and country offices**, ensuring that global priority-setting, normative guidance and product assessment are connected to country needs, regulatory pathways, procurement and implementation.

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Part I GETTING A PRODUCT DEVELOPED

Functions 01–04

01



● 2017 list

7 years

● 2024 list

WHO priority-setting for pathogens and neglected diseases

Diseases affecting neglected populations and offering limited commercial returns are often under-prioritized by market-driven R&D. WHO's R&D Blueprint for epidemic and pandemic threats, Bacterial and Fungal Priority Pathogens Lists, Neglected Tropical Disease (NTD) Road Map and disease-specific priorities help identify unmet needs and guide research investment. Together, these mechanisms should address neglected parasitic diseases alongside bacterial, fungal and viral threats. By providing a shared reference for funders, developers, regulators and health ministries, WHO priorities can align efforts and reduce duplication. The Bacterial Priority Pathogens List has informed GARDP's Gram-negative portfolio. Sustained WHO-led priority-setting is equally important for therapeutics, diagnostics and other technologies addressing NTDs and other neglected diseases. Identifying priorities is only the first step; they also require regular review and translation into actionable R&D agendas. The seven-year interval between the 2017 and 2024 bacterial lists highlights the importance of predictable reviews. **WHO should publish clear review cycles and criteria for earlier updates, assign responsibility for each mechanism, and ensure priorities reflect evolving epidemiology, resistance, country needs and R&D gaps.**

02



40 AMR research
priorities, 2023–2030

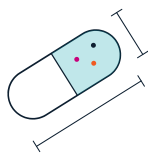
Research agendas and R&D roadmaps

Naming a priority pathogen is not a development plan. An agenda turns a priority into a sequence: which evidence gap to close first, which product to build next — and that is what lets PDPs and funders align instead of duplicating each other. WHO does this well where it does it. The Global Strategy for TB Research and Innovation was adopted by the World Health Assembly in 2020 and the 2023 AMR agenda set 40 research priorities to be addressed by 2030. WHO's guideline groups identify research gaps, but these require further prioritization using rigorous methodologies and consideration of current unmet needs.

Building on WHO's work to strengthen research priority-setting, WHO should translate the resulting priorities into actionable, regularly updated disease-specific or cross-cutting R&D agendas across malaria, NTDs and other neglected or pandemic-prone diseases, with clear responsibility for maintaining each agenda, timelines and priorities that funders and developers can act upon.

03

Target product profiles



A WHO Target Product Profile (TPP) tells developers what a product needs to achieve to work in the real world. WHO also develops Preferred Product Characteristics (PPCs) and Target Regimen Profiles (TRPs), which provide complementary guidance for product and regimen development. This is particularly important where commercial incentives are weak. WHO provides an authoritative public health signal, while PDPs translate that signal into development programmes. DNDi uses TPPs to guide its neglected disease portfolios, TB Alliance applies target profiles to the development of shorter and more practical TB regimens, and WHO’s March 2026 antibacterial TPPs provide direction for developers such as GARDP by incorporating not only efficacy and safety, but also affordability, access and stewardship.



TPPs should therefore be treated as a core global public good, not simply as technical guidance. They help align developers and funders around products that meet the needs of patients and health systems, particularly in high-burden countries, and can help reduce the risk of investing in products that ultimately cannot be used or accessed where they are most needed. **We recommend that WHO protect and adequately resource its TPP function, systematically engage PDPs and high-burden countries in their development and review, and keep TPPs current as science, pipelines and country needs evolve.**

04



10

weeks to joint written guidance

1

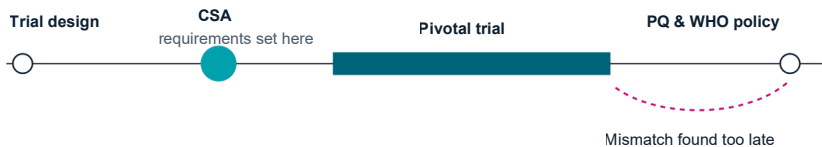
entry point

\$0

free of charge

Coordinated scientific advice before pivotal trials

WHO’s Coordinated Scientific Advice (CSA) procedure lets a developer approaching late-stage trials get joint written guidance from the relevant technical department and the Prequalification Team simultaneously — one entry point, ten weeks, free of charge. It answers the question that otherwise gets answered too late: is this evidence package sufficient for both prequalification and WHO policy development. WHO’s own aim is that these requirements are built into trial design rather than determined afterwards.



A mismatch discovered after a pivotal trial means further studies and years lost.

This early identification and integration of WHO scientific advice helps to substantially reduce the costs and expenses of PDPs, since a mismatch discovered after a pivotal trial means further studies, years lost and unaffordable monetary expenditure for a not-for-profit developer. Currently, WHO recommends the request should be from whoever will file for prequalification. For many PDPs, this is often a manufacturing partner that is unlikely to be chosen until years after the trial is designed.

We recommend that WHO should adequately resource the procedure, make it a standard requirement for products against priority pathogens and neglected diseases, and confirm that the developer or organization running the trial can request use of the procedure.

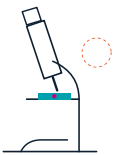
Part II

GETTING A PRODUCT TO PATIENT

Functions 05–09

05

Treatment guidelines and policy recommendations



Regulatory approval is a formal authorization; a WHO recommendation is what ministries and procurers act on. For medicines serving very small populations, a WHO recommendation doesn't follow the market — it creates it. This is because a WHO guideline is the one signal every national programme accepts. For example, Kenya, Ethiopia and Uganda held back their own leishmaniasis revisions until WHO published it in July 2026. New treatments and health technologies developed by PDPs often require new or updated WHO recommendations to support their adoption in countries. The challenge is to ensure that these recommendations are issued in a timely and predictable way. For example, WHO's guideline development group reviewed evidence on new leishmaniasis treatments in November 2023, while updated recommendations were published in July 2026. This illustrates how timelines for WHO guidance can affect planning for national guideline updates.



Bars drawn to the same monthly scale.

What varies is the machinery behind it, and when the machinery needed to reissue guidelines exists and is well-resourced, it can support timely recommendations and their implementation. For example, WHO's TB programme issued rapid communication on BPaLM in May 2022, approximately seven months before the full guidelines were published in December, signalling the forthcoming changes to countries. **A strong culture of innovation in WHO should aim for rapid and optimized alignment of the prequalification process, the development of guidelines and treatment standards, and the introduction of new medicines in countries, while maintaining the highest standards of patient safety and evidence-based policy making.**

06

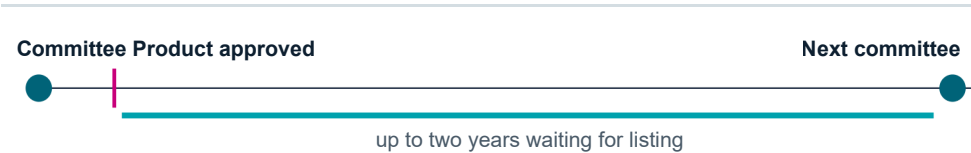
Essential Medicines List



150+

countries build national lists from the model list

The Essential Medicines Listing (EML) is what turns a WHO recommendation into a national procurement budget line. It works because ministries and procurers treat the model list as the benchmark — over 150 countries build their national lists from it. It has included products from many PDPs: ravidasvir for DNDi; the components of BPaLM for TB Alliance; and cefiderocol for GARDP. But the Expert Committee only meets once every two years, so a product approved just after a meeting has to wait two years for the next Expert Committee meeting. This can mean that countries instead have to adapt on their own timetables without detailed WHO guidance for that step. To improve WHO responsiveness, WHO should open a standing out-of-cycle route for first-in-class medicines against priority pathogens, and pair each update with adoption guidance countries can use.



07



~70%

of countries have
limited regulatory
capacity



Prequalification and risk-based assessment

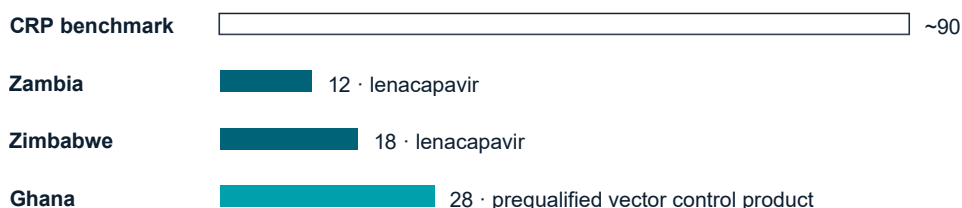
WHO prequalification provides a common quality benchmark for international and pooled procurement. It does not replace national approval, since countries can authorize products through their own regulatory or reliance pathways, sometimes before WHO PQ. But without PQ or another recognised reference assessment, access can remain piecemeal, particularly given that around 70% of countries have limited regulatory capacity. For medicines, manufacturers can only seek PQ for products covered by an active Expression of Interest (EOI). These are shaped by WHO disease programmes and clinical experts and are generally linked to WHO guidelines and the Essential Medicines List. This can leave a gap between WHO identifying an important product need and that product's eligibility for PQ. WHO is already moving to align its normative and PQ processes more closely. **It should make this systematic and start earlier—using its priority-setting, TPPs and other product guidance to inform PQ eligibility, so quality assurance can move alongside product development and national access, rather than follow later.**

08



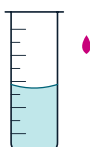
Regulatory reliance and collaborative registration

Approval in one country does not make medicine available in another. WHO's Collaborative Registration Procedure (CRP) lets a national regulator use an assessment already performed by WHO prequalification or a trusted authority and reach its own decision in about 90 working days. The country still decides. For example, Zambia approved lenacapavir in 12 working days last November, Zimbabwe in 18 days and Ghana approved a prequalified vector control product in 28 days. Every product that PDPs launch has to be registered in multiple countries, and no PDP has the required regulatory capacity. WHO regulatory mechanisms were built precisely to overcome this limitation of each PDP. But it only runs where a country has signed up, and if the manufacturer initiates and consents to share the reports. That places the trigger with a commercial partner rather than the developer. WHO should enlist more countries and make collaborative registration the standard route for prequalified medicines against priority pathogens and neglected diseases.



Days to national approval (Zambia and benchmark in working days).

09



Norms, standards and reference materials

WHO produces the reference materials that let a result from one laboratory be trusted in another, including the international standards used to calibrate biological tests, the International Pharmacopoeia and the official name every medicine is given. They work because measurement only means something if everyone measures against the same reference, and no other body can make a single standard universal. Everything PDPs develop, analyze and research depends on common international standards. A potency test or a bioequivalence study, for example, only travels because these standards exist. They are also among the smallest and least visible items in WHO's budget, which is what puts them at risk in a smaller structure. **WHO should keep these functions as named line items rather than integrating them into a general pool.**

Why this matters

Without institutional guidance, partnership, technical standards and country-informed standards, PDPs would be unable to carry out their core functions successfully.

One critical priority for any WHO reform process is not to focus on where these functions are placed in WHO, but that these functions are recognized for their critical importance, that they remain visible, sufficiently resourced, clearly accountable and connected across WHO. PDPs are also adapting to a more constrained environment, as reflected in the June 2026 agreement between DNDi, GARDP and MMV to explore pooling resources and reducing duplication.

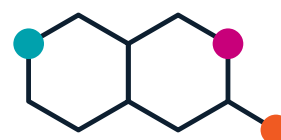
Reform should strengthen WHO's ability to enable needs-driven innovation, such as by identifying research priorities and supporting countries in making informed decisions about new health technologies. **Success should be judged by the timeliness, quality and usefulness of these functions, and their contribution to equitable access and public health outcomes.**

VISIBLE

SUFFICIENTLY RESOURCED

CLEARLY ACCOUNTABLE

CONNECTED ACROSS WHO



About the partners



ABOUT GARDP

GARDP is a not-for-profit global health organization driven to protect people from the rise and spread of drug-resistant infections, one of the biggest threats to us all. By forging the public and private partnerships that matter, we develop and make accessible antibiotic treatments for people who need them. GARDP is registered under the legal name GARDP Foundation in Switzerland.

gardp.org



The Not-For-Profit Pharmaceutical Company

ABOUT MDGH

Medicines Development for Global Health (MDGH) is a not-for-profit pharmaceutical company developing new medicines to ease the burden of neglected diseases on underserved communities worldwide. MDGH is currently developing two medicines: moxidectin and dovramilast. Together, these medicines target seven different neglected diseases that collectively affect more than 1 billion people.

www.medicinesdevelopment.com/



ABOUT DNDi

The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit medical research organization that discovers, develops, and delivers safe, effective, and affordable treatments for neglected people. DNDi is developing medicines for sleeping sickness, leishmaniasis, Chagas disease, parasitic worm diseases, mycetoma, dengue, paediatric HIV, advanced HIV disease, cryptococcal meningitis, and hepatitis C. Its research priorities include children's health, gender equity and gender-responsive R&D, and diseases impacted by climate change. Since its creation in 2003, DNDi has joined with public and private partners across the globe to deliver 17 new treatments, saving millions of lives.

dndi.org



ABOUT MMV

MMV is a not-for-profit product development partnership working to discover, develop and deliver medicines to treat, prevent and eliminate malaria. Since 1999, over 1.4 billion people have benefited from our co-developed medicines. With over 600,000 malaria deaths every year, we unite partners to close remaining antimalarial access and innovation gaps.

www.mmv.org