



# How to accelerate health product development for diseases of poverty

Overview of a report from TDR, the Special Programme for Research and Training in Tropical Diseases, on how an R&D Fund could be set up by the World Health Organization (WHO).

## A health product R&D funding crisis

Today, a mere 1% of the new chemical compounds registered between 2000 and 2011 were approved for diseases of poverty, even though these diseases make up 11% of the disease burden. There are two key reasons for this. One is the absence of global level agreements on research and development (R&D) funding priorities and coordination around these priorities.

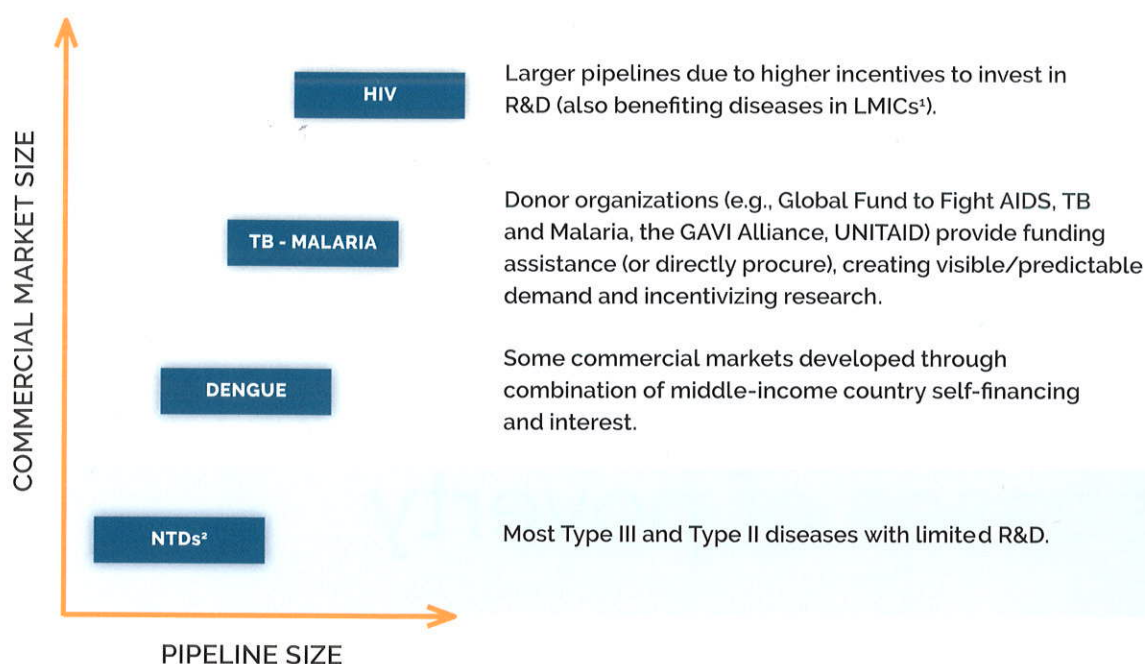
The other is the lack of appropriate funding mechanisms to support R&D for drugs, diagnostics and vaccines where there are few commercial incentives. The outbreak of Ebola in 2014 and a dramatic rise in microbial drug resistance have highlighted the critical gaps that still exist in the R&D of health products for diseases of poverty.

Infectious diseases do not respect borders. This poses a real and serious threat to global health security. The funding crisis, the scientific complexity and protracted timelines of R&D for many of the new discoveries are major challenges.

World Health Organization Member States have asked for a novel approach to these challenges. No one country can meet the challenge, so what can be done?

“ The research and financing needs differ by disease. In some cases diagnostics are most critical, in others drugs and vaccines. There are no global level agreements on these. ”

## IMPACT OF MARKET ON PRODUCT PIPELINE



- Even diseases with larger pipelines, such as HIV/AIDS or malaria, still have serious and specific unmet needs.
- This underscores the need to identify R&D gaps for all Type III and II diseases.
- A full review would be performed by the WHO Global Observatory on Health R&D.

<sup>1</sup> LMICs: Low- and Middle-Income Countries;

<sup>2</sup> Such as schistosomiasis, hookworm, etc.

“ Drugs, diagnostics and vaccines for diseases of poverty that have little or no commercial market will not be brought on stream without dramatic changes to the commercial model. ”

### A proposed new approach

In 2014, the World Health Assembly (WHA) requested that the WHO Director-General explore the possibility of a pooled fund for voluntary contributions toward R&D for diseases of poverty. The Special Programme for Research and Training in Tropical Diseases (TDR) – hosted at WHO and co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Fund (UNDP), the World Bank and WHO – was selected to investigate how a fund could be developed and asked to report back in early 2016. TDR undertook an extensive consultation with stakeholders from the public and private health product development sectors including the product development partnerships, academics, industry, civil society and the donor community.<sup>3</sup>

A comprehensive analysis has been completed and a full report on the findings is available on the TDR website ([www.who.int/tdr](http://www.who.int/tdr)), starting 20 February, 2016.

<sup>3</sup> This work was supported by a CHF 2 million designated award from the Swiss Agency for Development and Cooperation (SDC).

“ First and foremost, public health need in resource-poor settings must drive strategic decisions about which R&D projects to fund. Everything must be focused on ensuring access to those most in need. ”

The report covers three areas:

- A financial model to support health R&D;
- Mapping of the health product pipeline; and
- Managing an R&D portfolio to incentivize innovation.

TDR is confident that, if requested, it can establish a transparent and efficient mechanism to manage the pooled fund and the portfolio of health product R&D projects.

Disease-endemic and donor countries would form part of this governance structure, opening the door to new funders. For example, Brazil, India and South Africa are already contributing to support demonstration projects in this area.

The advantage of a pooled fund under WHO is that it allows for all Member States to participate at any level, sharing both the risks and potential benefits such a fund could bring.

## DISEASES THAT WOULD QUALIFY FOR THE PROPOSED FUND

The diseases of poverty that mostly affect developing countries and urgently need investment in R&D are:

- **Type III diseases** found mostly in developing countries;
- **Type II diseases** that are in all countries, but the disease burden is greatest in the poorest; and
- **Type I diseases** that occur in all countries but where the R&D needs in developing countries are not being met.

## How a fund would work

The proposed fund would support a portfolio of the most promising health products in countries where the public health need is greatest. It would provide incentives to cover the risk of R&D for products where there is no commercial market.

The proposal is for the fund to sit within the WHO structure and for it to be managed by TDR. It would provide a mechanism to cost-out priorities set at a global health level, which would come from the WHO Prioritization Mechanism. Priorities will be based on data published by the new WHO Global Observatory on Health Research & Development.

“ It is vitally important to balance quick wins with the longer term projects that can have most impact but where there is market failure. Investment in products for persistent neglected diseases is crucial. ”

The following issues need to be considered by WHO Member States:

- A fund of sufficient scale (e.g., reaching US\$ 100 million annual disbursement after 5 years) should be set up;
- The fund's project portfolio should be varied, including both short-term repurposing and longer-term discovery efforts;
- The fund must be operated transparently, with clear objectives, and non-political, evidence-based decision-making processes; and
- The fund must have ways to accept 'new' funders and maximize leverage.

### A new financial modelling tool – P2I

TDR has developed a ground-breaking tool that provides a new and flexible approach to priority-setting and funding at the global level. Known as Portfolio-to-Impact (P2I), it models the timeline and minimum funding required to develop new drugs, diagnostics and vaccines for diseases mostly affecting developing countries.

## POTENTIAL HEALTH R&D FINANCING MECHANISM OPTIONS

Annual fund size <sup>4</sup> (in millions)	Description	If development starts in 2017, what is expected by 2030?
1 Passive coordination Up to US\$ 1 M	Define and communicate global priorities across diseases.	
2 Prioritization Forum Up to US\$ 5 M	Review funding directions with donors and evaluate if funding is aligned with global priorities.	
3 ~US\$ 15 M (small)	Fund 3-4 projects (unable to fund innovation focused projects).	3 simple repurposed drugs
4 ~US\$ 50 M (PDP size)	Fund 15-20 projects (including a few innovation focused projects).	1 simple New Chemical Entity (NCE)
5 ~US\$ 100 M (medium)	Fund 25-40 projects (including ~5 innovation focused projects).	1 complex repurposed drug
6 ~US\$ 300 M (large)	Fund 80-100 projects (can bring a novel intervention to approval).	1 simple biologic
7 >US\$ 500 M (global)	Fund 140-160 projects (can fund many projects in development in priority areas).	1 complex NCE

<sup>4</sup> Costs shown represent annual amount of funds for disbursement to support R&D from pre-clinical to phase III; costs related to management infrastructure and fund hosting are not shown.

“ P2I greatly assists the estimation of the potential long-term impact of a given funding scenario. ”

Using this tool, TDR has set out seven scenarios for a financing mechanism managed under WHO. P2I estimates how many products, new or re-purposed, simple or complex could be developed under such a mechanism.

The scenarios range from WHO acting primarily as a convenor to set priorities, through to the management of funds by TDR of different sizes (US\$ 15 to 500 million annually). These would directly support R&D from promising leads through to the launch of a new product.

This is the first time such a tool has existed. It makes it possible to estimate the minimum development costs and timeline for R&D from pre-clinical through Phase III trials. It accounts for in-kind contributions from public, not-for-profit and industry partners and excludes the costs associated with facilities, human resources and production.

P2I provides an overview of the options with different product archetypes, such as 'quick wins' or 'focused innovation'. P2I can estimate annual spending and the number of projects in the pipeline from 2017 to 2030 and presents a range of funding scenarios and what they can deliver.

## Mapping the health product pipeline

TDR recommends the creation of a new online resource that brings together in one place the R&D landscape for developing countries in a standardized way. This compendium of Ideal Product Profiles (IPP) or Target Product Profiles (TPP) allows for a complete mapping of the product pipeline against R&D activity. It forms a major part of the information needed to have a global conversation on health product R&D priorities and gaps and how these can be addressed.

The compendium would show which products, the funds needed and associated timescale to launch. It would also show orphan areas without support. TDR is currently working with partners to develop the norms and standards necessary to create such a resource. The compendium would be hosted by the WHO Global Observatory on Health R&D.

## Managing an R&D portfolio to incentivize innovation

TDR would build on its already established global network to convene and manage a new Scientific Working Group (SWG) of world-class experts to review and identify in a clear and transparent way which product development priorities to pursue.

The SWG would manage the selection, monitoring and evaluation, and financing of projects. TDR recommends that the SWG includes

“ The best in their fields of academia, industry, business and finance, and regulatory would coordinate their efforts to develop R&D pathways for individual health products. ”

members who have knowledge and experience of leading clinical development projects and making portfolio decisions; health systems in developing countries; financial or business development and assessing the potential of projects and teams; infectious diseases, and regulatory agencies.

This core SWG would be supplemented by specialized expert groups for individual priority disease areas and/or health interventions. The SWG would use an array of incentive mechanisms – from grant-funded push mechanisms to purchase-commitment type pull mechanisms to cover the risk of R&D.

## Ensuring global health security through innovation

The proposed new fund is part of a wider global strategy and plan of action on public health and innovation and intellectual property (IP) that WHO has committed to working on for many years. In 2003, the WHA established a Commission to look at the role of IP and innovation. The Commission report focused on how to incentivise R&D and provide the necessary funding for those diseases where the poverty of the populations affected means limited or no incentives for commercially-driven R&D.

**The development of a new R&D fund under WHO would create for the first time a mechanism to identify and cost out health products at a global level. The fund would ensure that any products that are developed would be affordable, accessible, acceptable and available to the countries that need them.**

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The Special Programme for Research and Training in Tropical Diseases (TDR) is a global programme of scientific collaboration established in 1975. Its focus is research into neglected diseases of the poor, with the goal of improving existing approaches and developing new ways to prevent, diagnose, treat and control these diseases. TDR is sponsored by the following organizations:

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