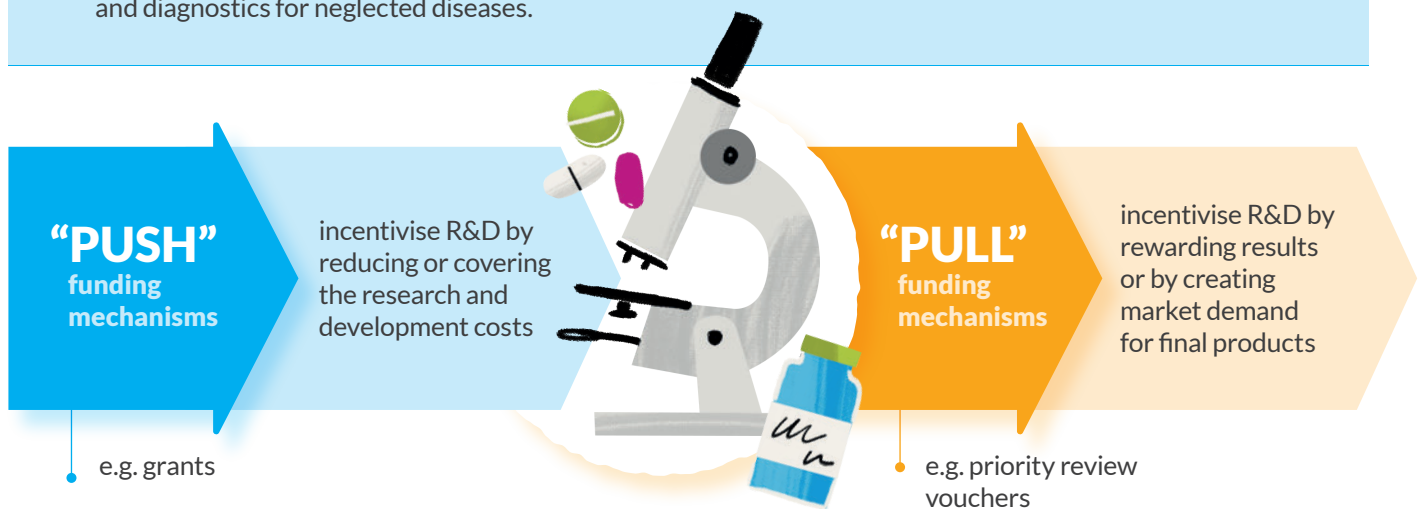


# BOOSTING GLOBAL HEALTH INNOVATION:

## EU pull funding mechanisms to accelerate the development of solutions for neglected diseases

This snapshot summarises the findings of a DSW study<sup>1</sup> that identified and evaluated pull mechanisms that could be introduced at EU level to encourage research and development (R&D) of new vaccines, medicines and diagnostics for neglected diseases.



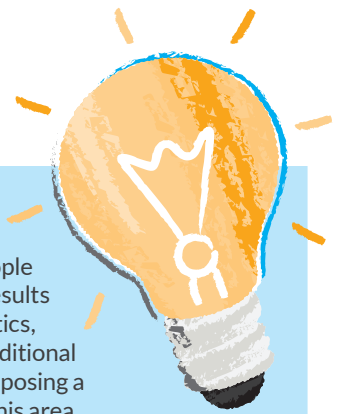
### PULL funding mechanisms can provide R&D support in different ways

There are different pull mechanisms, and some have mixed (push and pull) features. Some have been implemented (in other geographies or fields of research), whereas others have only been theorised so far:

- ▶ **Innovation hubs** promote portfolio funding and equitable partnerships
- ▶ **Impact bonds and milestone prizes** reward research progress and outputs
- ▶ **Priority review vouchers** reward regulatory approval and product launch
- ▶ **Advance market commitments and minimum revenue/prices** de-risk investments through financial guarantees

“*Innovation in Europe is losing ground compared to the US, for instance. We have very good centres of excellence and biotech but there is a lack of translating this academic know-how into products.*”

# KEY TAKEAWAYS FROM THE STUDY



## ▶ **The lack of tools against neglected diseases is a textbook case of market failure**

Neglected infectious diseases such as HIV, tuberculosis, malaria, and leprosy predominantly affect low- and middle-income countries (LMICs), impacting people with limited ability to pay for health products. This results in little market potential for developing new diagnostics, medicines, or vaccines. This market failure makes traditional market-based incentives such as patents ineffective, posing a major barrier to private sector R&D investments in this area.

## ▶ **Tackling neglected diseases with new and improved diagnostics, treatments, and vaccines is more urgent than ever**

Due to multi-faceted intersecting crises, climate change, increasing drug resistance, conflicts, and pandemics, the development of new tools to address the global burden of neglected disease is more needed than ever. R&D investments in this area also have many positive spillovers into other areas. For instance, the response to the COVID pandemic significantly benefited from earlier R&D targeting neglected diseases.

## ▶ **Global health innovation requires more funding as well as an enabling ecosystem**

Despite staggering societal and economic returns, investments in neglected disease R&D remain largely insufficient and scattered. An enabling ecosystem provides predictable and sufficient support throughout the R&D process. It requires funding and collaboration, but also adequate health and regulatory systems and a trained workforce to ensure the safety, quality, suitability, accessibility, and affordability of health products.

## ▶ **Product Development Partnerships (PDPs) are key drivers of global health innovation**

PDPs are non-profit organisations that facilitate public-private research cooperation. They can mitigate the financial risks of product development by pooling funds from multiple sources and by applying a portfolio approach where funds can be directed to successful candidates within the portfolio, and facilitate affordable access to health innovations. They are at the forefront of neglected disease R&D, from initial research to registration and access to products for patients in need.

## ▶ **EU push funding for neglected disease R&D drives health research, equity, and security**

EU funding has contributed to expanding our understanding of neglected diseases and resulted in new promising tools which are benefiting patients in Europe and around the globe. It has also supported a flourishing EU global health R&D ecosystem and enhanced Europe's epidemic preparedness and response capabilities. Many of these initiatives have been led by the Africa-Europe partnership EDCTP (European & Developing Countries Clinical Trials Partnership).

## ▶ **Pull funding mechanisms are essential to deliver impactful global health innovations**

Pull incentives facilitate the transition of health innovations from R&D stages to commercialisation and access, helping developers advance products through the final and costly development phase. When they reward product launches, pull mechanisms can also incentivise private sector participation and enhance affordable access to products. Ultimately, pull funding mechanisms help translate R&D into socioeconomic benefits, valorising public-private investments and collaborations.

**The EU lacks pull funding mechanisms for global health innovation**

The EU has various push funding mechanisms supporting neglected disease R&D, but no specific pull funding mechanism in the field. This hinders the EU's ability to fully leverage its R&D investments by transforming them not only into excellent science but also into tangible health innovations. New pull incentives would be a powerful addition to the EU's global health R&D toolbox, filling gaps in the current ecosystem and addressing some persisting barriers to neglected disease R&D.

**Pull incentives mobilise private sector investments and leverage European biomedical R&D expertise**

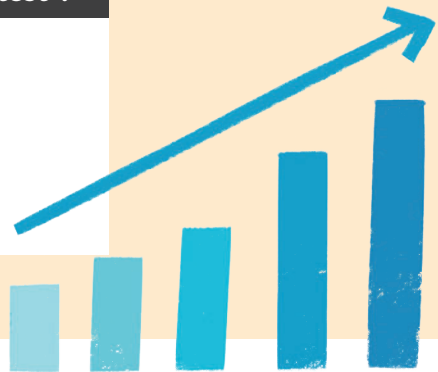
As the EU hosts a rich variety of organisations and research institutes spearheading neglected diseases innovation, EU pull incentives can mobilise additional private investments. This will harness the expertise and leverage the resources of the diverse European pharmaceutical industry and research-based organisations, maximising the impact of EU investments and fostering international collaborations.

**Assessment criteria**

To determine which incentives could realistically achieve results and be implemented in the EU, we conducted a thorough assessment against a set of criteria across the following dimensions:

- A general assessment:**
- Effectiveness
  - Efficiency
  - Fairness
  - Sustainability

- "The EU feasibility test":**
- Political feasibility
  - Legal feasibility
  - Financial feasibility

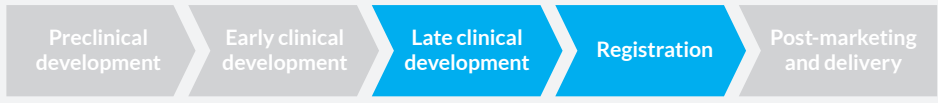


**THE RIGHT MIX OF PUSH AND PULL FUNDING**

Different funding modalities and pull incentives have the ability to stimulate R&D in different phases of research. Therefore, the only way to ensure a rich pipeline of product candidates and their progression towards reaching patients is **a healthy R&D ecosystem comprising push funding and complementary pull incentives!**

**Priority Review Vouchers**

This incentive contributes to **phases 3 and 4** of the R&D cycle.



**Innovation hub**

This incentive contributes to **phases 1 to 4** of the R&D cycle.



# PROMISING PULL MECHANISMS

“Pull mechanisms do not really exist for Neglected Diseases.”  
(Funder)

## 1: INNOVATION HUBS

**Innovation hubs** such as the Global Health Innovative Technology Fund (GHIT Fund), or the Research Investment for Global Health Technology Foundation (RIGHTS Fund), **offer predictable and sustainable R&D funding by supporting a portfolio of product candidates per organisation.** This can address major risks for organisations involved in neglected disease R&D: (1) those of having to reapply regularly for funding to

continue their work; and (2) those of losing all funding and staff due to a single project ‘failure’. This mechanism received the highest scores both for the general assessment and for EU feasibility. With additional funding, the EDCTP Association of the Global Health EDCTP3, which has extensive experience in neglected disease R&D and funding could potentially fulfil this role.

## 2: ORPHAN DRUG DESIGNATION

**The Orphan Drug Designation (ODD)** combines several pull and push incentive mechanisms that have **effectively encouraged the development of new medicines for rare diseases in the USA and the EU.** The mechanism scores very well in terms of EU feasibility, but not as well in terms of the general assessment. While neglected diseases products have often received ODD, their

primary target is people living in LMICs. The limited purchasing power of patients in LMICs pushes prices down, which makes the extension of the exclusivity period in the EU market less valuable for neglected diseases products. As the mechanism is not able to create a more attractive market for developers, it cannot effectively encourage R&D for neglected diseases.

## 3: PRIORITY REVIEW VOUCHERS

**Priority Review Vouchers (PRV)** reward product developers that successfully launch a neglected diseases product with a tradeable voucher that grants faster regulatory review of a second, more profitable, product. They are among the most feasible mechanisms in the EU and score well on the general assessment. The potential value of an EU PRV has recently been evaluated by a scientific study published in BMJ. PRVs are also among

the few pull funding mechanisms for neglected disease R&D that have actually been implemented in the USA and DSW’s proposal for an EU PRV incorporates lessons learned and adapts the mechanism to the EU context. **A PRV does not require any upfront payment by the public sector, it does not extend any exclusive rights and does not block the entry of generics to the market.**

## 4: MILESTONE PRIZES

**Milestone prizes** provide sequential funding upon the successful completion of an R&D milestone. They score well in the general assessment. While research prizes are common in the EU, milestone prizes have never been

tested. Milestone prizes provide **more predictable funding across the R&D cycle, as well as reputational benefits to companies and to the EU when rewarding scientific progress.**

“Push funding for clinical trials, especially in early phases, is essential.”  
For-profit company

# RECOMMENDATIONS



# 1

## **PUSH AND PULL FUNDING MECHANISMS ARE NEEDED TO EFFECTIVELY STIMULATE NEGLECTED DISEASE R&D, AND THE GREATEST GAP IN THE EU'S ECOSYSTEM IS ON THE PULL SIDE.**

The Global health EDCTP3 is a critical initiative supporting early and mid-stage clinical research, but it needs complementary pull funding mechanisms to translate late-stage research into products.



# 2

## **INNOVATION HUBS CAN BE INTRODUCED IN THE EU WITH MINIMUM REFORMS, AND MAKE A MAJOR CONTRIBUTION TO NEGLECTED DISEASE R&D.**

For instance, a European innovation hub modelled after the GHIT fund or the RIGHT Foundation could improve the traditional PPP/ PDP model by leveraging strategic partnerships to work across a project portfolio with a targeted mission or disease. This model can be synergized with existing initiatives such as the EU Health Emergency Preparedness and Response Authority (HERA), EDCTP, and Horizon Europe.



# 3

## **A PRIORITY REVIEW VOUCHER PROGRAMME CAN BE INTRODUCED IN THE EU WITHOUT IMPOSING COSTS ON PUBLIC BUDGETS.**

An EU PRV can rely on existing functions of the European Medicines Agency (EMA) and make an important contribution to incentivise neglected disease R&D.



# 4

## **PULL FUNDING MECHANISMS NEED TO BE ADAPTED TO THE PARTICULAR SITUATION.**

Multi-stakeholder discussion and further analysis are needed to optimally design the most promising incentives so that they can effectively stimulate neglected disease R&D and be viable and synergetic within the EU ecosystem. Several factors, such as the particular disease(s) or product, legal, political and financial conditions, R&D needs, and others, determine which mechanism or combination of mechanisms work best.



# 5

## **PRVS, COMBINED WITH MILESTONE PRIZES COULD ADDRESS THE WHOLE R&D CYCLE, UP TO ACCESSIBILITY OF PRODUCTS IN A COMPLEMENTARY WAY.**

This is because, combined with adequate push funding, different pull incentives can stimulate R&D in different phases of research.



# 6

## **THE EU HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA) COULD PLAY A LEADING ROLE IN IMPLEMENTING SOME OF THESE MECHANISMS.**

This would be similar to HERA's work on pull mechanisms for the development of new antimicrobials and can build on its experience with pull mechanisms for COVID-19 and Mpox vaccines. As recently suggested by the European Parliament, HERA's mandate could in principle include neglected diseases and other areas of unmet medical need, and this possibility should be further studied.<sup>4</sup>

Deutsche Stiftung Weltbevölkerung (DSW) is a global health NGO engaged in sexual and reproductive health and rights (SRHR) and global health research and innovation (R&I) – for poverty-related and neglected diseases and Women's health.

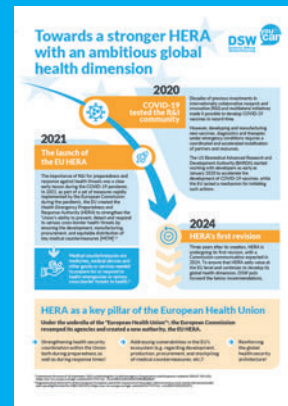
## ADDITIONAL RESOURCES:



[Exploring Pull Mechanisms to Encourage Neglected Disease R&D in the EU](#)



[Making a Case for a Priority Review Voucher Programme in the EU](#)



[Towards a stronger HERA with an ambitious global health dimension](#)