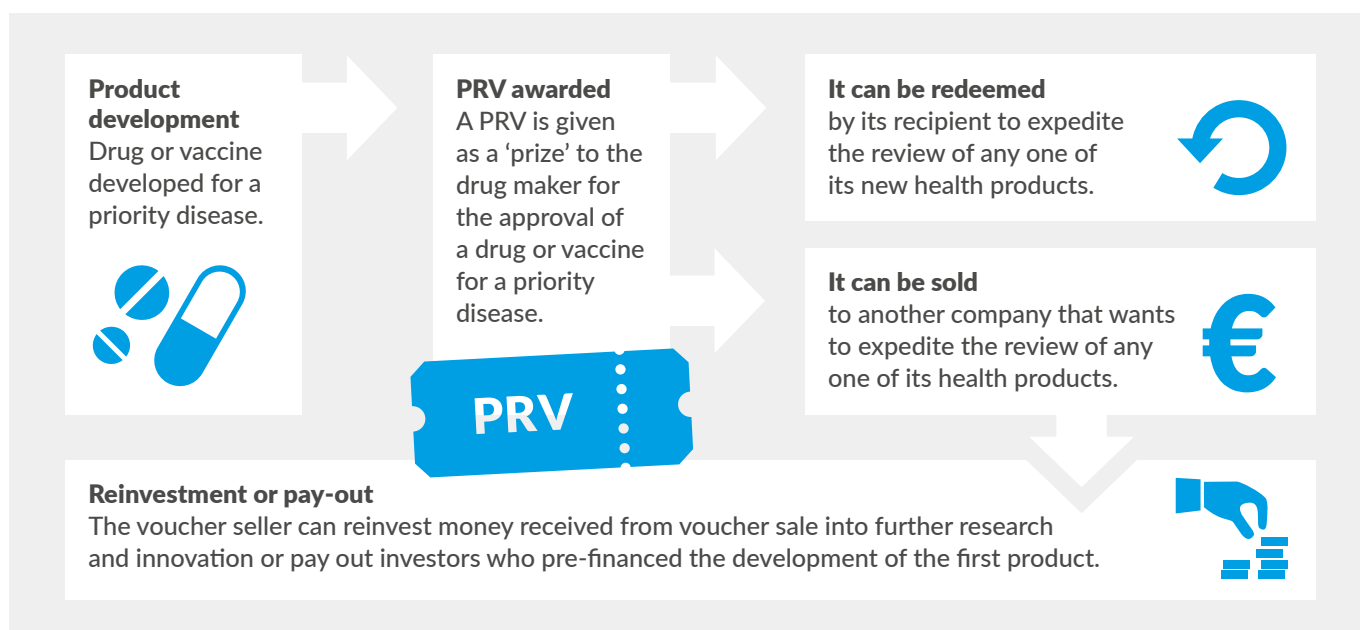


# MAKING A CASE FOR A PRIORITY REVIEW VOUCHER PROGRAMME IN THE EU

**Vaccines and treatments to tackle neglected infectious diseases are limited**, despite affecting around two billion people across the world. New tools hold a huge potential in unlocking major health benefits and driving sustainable social and economic development. However, progress in their development is slow, in part due to limited funding for research and innovation. **The Priority Review Voucher or PRV is a pull incentive that rewards product developers** that successfully develop an innovative health product with a tradeable voucher that grants priority review of a second product. First introduced in the USA in 2007, the Food and Drug Administration's (FDA) [Tropical Disease Priority Review Voucher Programme](#) has since catalysed the availability of groundbreaking innovations, including the [first vaccine against Dengue fever](#), a [radical cure for malaria](#) and [the first new tuberculosis drug in forty years](#).

## HOW DOES THE PRV WORK?



## WHAT ROLE OF A PRV PROGRAMME IN THE EU?

A leader in global health, **the European Union (EU) recently reiterated its commitment to ensuring that innovative vaccines, treatments, and diagnostics for neglected infectious diseases are developed and globally accessible** in its [new global health strategy](#). The EU's investment, including via Horizon Europe and the European Developing Countries Clinical Trials Partnership ([EDCTP](#)) contributed significantly to the existing [pipeline](#) of candidates.

While new health tools can achieve tremendous health, societal and economic benefits, their journey through the research pipeline is long, risky, and expensive. Introducing **a PRV programme in the EU could incentivise product development, and pull candidates through the last costly stages of development**, thereby **bridging the EU's established push funding efforts**, its unique [EUM4all](#) procedure and its support to [regulatory](#) and [manufacturing](#) capacity strengthening in Africa.

# BRIDGING EU SUPPORT FOR NEGLECTED INFECTIOUS DISEASES PRODUCT DEVELOPMENT



## HOW WOULD THE PRV PROGRAMME BE IMPLEMENTED IN THE EU?

The European Medicines Agency (EMA) would host the PRV programme under its centralised authorisation procedure, eligibility focuses on neglected disease products. The PRV programme could be further integrated with existing EMA procedures, including the **PRiority MEDicines scheme (PRIME)**, granting early scientific dialogue to developers, and complement the **EUM4all programme**, a coordinated mechanism between the EMA, the World Health Organization (WHO) and national regulators, providing a scientific opinion on high priority human medicines for use outside the EU. This would reinforce the attractiveness and effectiveness of the programme. Furthermore, the voucher programme could also be designed to provide faster pricing and reimbursement decisions (member state competence) or grant access to joint health technology assessments which could increase its value.

### Voucher Eligibility



The authority to define, adjust and approve eligibility should be granted to the European Commission, while the EMA, HERA and ECDC can provide recommendations. As with the FDA, the EMA should also have a public docket to which interested parties can submit considerations for eligibility.

### Voucher Approval



Granted once the product receives market authorisation and not before.

As with the FDA, the EMA could provide a preliminary, nonbinding opinion before authorisation that a given application appears to meet the criteria for voucher eligibility.

### Redeeming the Voucher



The increased need for capacities will be balanced out by applying:

A user fee of 1 million EUR, revised annually by the EMA. <sup>1</sup>

A notice period, requiring a voucher user to give the EMA 90 days' notice before use. <sup>2</sup>

*"An EU priority review voucher programme for neglected infectious diseases would incentivise developers to invest in research and development for these often overlooked diseases, which disproportionately affect the world's most vulnerable populations. **By implementing a priority review voucher programme, the EU has an opportunity to harness the contribution of other EU-led initiatives in this field, such as the EDCTP.** In promoting scientific progress, and fostering collaboration through a priority review voucher programme, the EU can boost its contribution to the global effort to combat neglected infectious diseases. Together, we can bring hope and health to those who need it most."*

#### Professor John Reeder

Director of TDR, the Special Programme for Research and Training in Tropical Diseases and Director of the Research for Health Department at the World Health Organization





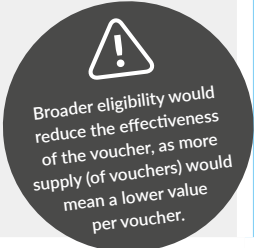
*"As an organisation dedicated to developing safe and effective vaccines and antibodies against poverty-related, neglected and emerging infectious diseases, **we recognise the immense potential of an EU Priority Review Voucher Programme in advancing our mission.** Such a programme would significantly enhance our ability to bring life-saving products to market. An EU Priority Review Voucher Programme would help to attract investment in our work tackling complex scientific challenges and support the delivery of new tools to better protect the world from existing, and future disease threats."*

#### Hester Kuipers

Executive Director, Europe, IAVI



# HOW WOULD A EUROPEAN PRV PROGRAMME COMPARE WITH THE USA'S PROGRAMME?

		
<b>Disease scope/ eligibility</b>  	<p>Tuberculosis, malaria, neglected tropical diseases and emerging infectious diseases affecting low- and middle-income countries.<sup>3</sup></p> <p>The European Commission could amend the law through a delegated act to add/ remove diseases following health/ scientific developments.</p>	<p>Tuberculosis, malaria, neglected tropical diseases and emerging infectious diseases affecting low- and middle-income countries.<sup>3</sup></p> <p>US Congress can amend the law to add/ remove diseases following health/ scientific developments.</p>
<b>Product scope</b>	Drugs and vaccines	Drugs and vaccines
<b>Novelty requirements (First product)</b>	<p>The active ingredient must not have been registered for human use with a <u>WHO listed authority</u> (e.g. the FDA) for more than two years. (This will allow for products to benefit from both the USA and EU vouchers, creating a more powerful incentive)</p> <p>Combination therapies must have at least one active ingredient that applies to the above requirement.</p>	<p>The active ingredient must never have been registered with the FDA. (This means products that have registered in the EU are still eligible and could thus benefit from both vouchers)</p> <p>Combination therapies must have at least one active ingredient that applies to the above requirement.</p>
<b>Access requirements</b>	An access plan is required. Availability is likely also to be fostered by other EU initiatives, including EDCTP legally obliging affordable access, by EUM4all facilitating registration, and Team Europe Initiatives facilitating local manufacturing.	Access plan is required.
<b>Time gains</b>	6 months (on average)	4 months (on average)
<b>Value</b>	100M EUR (estimate based on conservative economic modelling) <sup>4</sup>	100M USD (average)
<b>User fee for redeeming vouchers</b>	1 million EUR (with discounts for SMEs and not-for-profits)	1.5 million USD (with discounts for SMEs and not-for-profits)

1 The EMA current fee for applications for marketing authorisation of human products is 345,800 EUR. Our proposed fee would not only offset the costs of the programme but could be an income-generating activity for the Agency.

2 This is consistent with the fact that the EMA's accelerated assessment must be requested at least 2-3 months before the submission for marketing authorisation.

3 Tuberculosis, Malaria, Blinding trachoma, Buruli ulcer, Cholera, Dengue/ Dengue haemorrhagic fever, Dracunculiasis (Guinea-worm disease), Fascioliasis, Human African trypanosomiasis, Leishmaniasis, Leprosy, Lymphatic filariasis, Onchocerciasis, Schistosomiasis, Soil-transmitted helminthiasis, Yaws, Filovirus Diseases, Zika Virus Disease, Chagas disease, Neurocysticercosis, Chikungunya Virus Disease, Lassa Fever, Rabies, Cryptococcal Meningitis, Brucellosis, Opisthorchiasis, Paragonimiasis

4 2023 data is under analysis.

5 U.S. Government Accountability Office. "Drug Development: FDA's Priority Review Voucher Programs". (2020). Available at <https://www.gao.gov/products/gao-20-251>; This study found that incentive programmes are factored into companies' decisions to pursue neglected disease R&D. Mukherjee, S. "The United States Food and Drug Administration (FDA) regulatory response to combat neglected tropical diseases (NTDs): A review". PLoS Negl Trop Dis. (2023) This study found that since the creation of the PRV, the development of drugs for these tropical diseases has increased but not uniformly across all diseases. Kerr K., Henry T.C., and Mille K.M. "Is the priority review voucher program stimulating new drug development for tropical diseases?" PLoS Negl Trop Dis. (2018). - This study found positive but not statistically significant effects on stimulating R&D. Aerts C., Barrenho E., Miraldo M., and Sicuri E. "The Impact of the Priority Review Voucher on Research and Development for Tropical Diseases" Pharmaceut Med. 36(3): 189-197. (2022). - This study found that the programme was not associated with an increase in innovative, early-stage development for neglected tropical disease drugs starting clinical testing. Jain, T. Hwang, J.M. Franklin, and A.S. Kesselheim, "Association of the Priority Review Voucher with Neglected Tropical Disease Drug and Vaccine Development," JAMA, vol. 318, no. 4 (2017). However, this may be the result of decreased "push funding" for neglected tropical disease R&D which in 2022 fell to its lowest total since 2009 (G-FINDER report 2022).

## FREQUENTLY ASKED QUESTIONS

### Is a priority review voucher worth 100 million EUR enough?

If a product can receive both FDA and EMA vouchers then the reward is 200 million EUR. This can be sufficient to pull a drug or a vaccine through later stages of development and thus incentivise companies to make such investments or provide not-for-profit research organisations with an investment case.

### Does the priority review voucher delay the entry of generics?

The PRV, unlike other voucher programmes, would not extend exclusivity. It could even reduce exclusivity for the voucher-using product. In both the EU and the USA, patents are extended to account for lost regulatory time. As the voucher would shorten the regulatory time, it would result in a patented product entering the market earlier, yet not for an extended period of exclusivity.

### Does the priority review voucher delay the approval of other health products?

Limiting the eligibility for a PRV works to safeguard the value of the voucher and the impact on the regulator. Based on the number of vouchers awarded in the US and the number of product candidates in the pipeline, we estimate only two vouchers will be awarded per year. Since the introduction of the PRV in the USA, the FDA has consistently met its obligations of six months for priority and ten months for standard review, as is expected for the EMA given the measures outlined above. [The EU plans to grant additional capacities to the EMA.](#)

### How effective is the priority review voucher in incentivising neglected disease product development?

The limited empirical research on the USA's programme suggests that PRVs are a factor in product development decisions and that the tropical disease voucher programme has had positive albeit weak effects in stimulating neglected disease product development. While the creation of two additional PRV programmes in the USA was likely detrimental to the effectiveness of the tropical disease programme, an EU PRV could contribute to enhancing the effectiveness of the FDA's programme by providing a bigger combined incentive for neglected disease product development. The PRV's effectiveness will also depend on the availability of complementary push-and-pull funding programmes for neglected disease research and product development.<sup>5</sup>

## HOW YOU CAN SUPPORT NEGLECTED INFECTIOUS DISEASE PRODUCT DEVELOPMENT



**Work towards the introduction of a priority review voucher and other complementary pull funding mechanisms** (e.g. prizes or advanced market commitments) to support neglected disease product development in the EU



**Amplify calls for increased and sustained push funding** for neglected disease research and product development



**Promote public-private collaborations** to facilitate knowledge sharing and resource pooling



**Support the strengthening and harmonisation of medicine regulatory and manufacturing capacities** in low- and middle-income countries

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