

Reflection paper on the AMR Action Fund

About the BEAM Alliance

The BEAM Alliance (Biotech companies from Europe innovating in Anti-Microbial resistance research) represents over 60 European SMEs that develop solutions to fight antimicrobial resistance at a European and national level. The BEAM members are collectively developing over 140 new, diversified R&D projects focused upon prevention, diagnosis and cure of microbial infections. The goal of the BEAM Alliance is to maintain and promote awareness of SME-driven innovation in the field and to support policymakers in understanding economic business models around AMR.

The need for a dedicated AMR fund

Since its inception, the BEAM Alliance has been central in the call for a dedicated fund to tackle antimicrobial resistance (AMR). This key ask featured prominently in our very first <u>position paper</u>, in 2015, as a possible solution to the funding challenges faced by small and medium-sized enterprises (SMEs) in the development of innovative antimicrobials.

Over the past years, BEAM has also contributed to the work led by the World Health Organization (WHO) and the European Investment Bank (EIB) in designing a <u>financial model for AMR funds</u>. The model enables users to estimate the potential returns on investments into the fund given the information available on R&D costs, the rate of progression through development phases and potential revenues from successful products.

Despite their essential role in modern medicine, antimicrobials offer a low return on investment, given their low prices and purchased volumes. This market failure, coupled with scientific challenges, has led major pharmaceutical companies to stop investing in the field.

SMEs are thus the main actors in the design of new products to curb AMR, providing more than 80% of the approximately 400 antibacterial preclinical projects. Their struggle to find private investors to carry innovative products through clinical development is a serious constraint in the fight against AMR. A dedicated AMR fund is therefore a pressing need to fight what could become the next global health crisis.

The AMR Action Fund is highly welcome

The BEAM Alliance applauds the launch of the <u>AMR Action Fund</u>, and the promise of a long-awaited, and vital funding vehicle backed with nearly US\$ 1 billion to respond to the AMR threat. Although the Fund's detailed process and conditions are yet to be confirmed, its backbone is in place and it is financially supported by over 20 of the world's leading pharmaceutical companies.

As of today, the Fund has nearly \$ 1 billion to invest through equity or convertible debt; in addition, it may also provide in-kind drug development support where relevant. Over a 5-year period, 15 to 20 projects or companies are expected to benefit from the proposed investment, which does not foresee a pre-defined ticket: the invested amount will depend on the projects' or companies' needs and profile.

The Fund's main focus will be in supporting late-stage clinical development. Funded projects should be phase 1 or later of new, directly-acting antibacterial compounds (small molecules, phages, biologics, etc.) and should target priority pathogens (WHO and CDC threat lists). An independent Scientific Advisory Board (SAB) will be in charge of selecting the projects to be backed by the Fund, which aims to deliver 3-4 new antibacterial agents to clinical practice by 2030.

The AMR Action Fund thus represents a great opportunity for SMEs to fund capital-intensive, late-stage developments. Nevertheless, BEAM believes that, to deliver a sustained pipeline of products to meet the evolving threat of AMR, we need diversified armamentarium. We thus call for a broader scope of eligible projects, including non-traditional approaches, since their potential is now widely recognised by key stakeholders such as the WHO and Pew Trust.

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https://www.nature.com/articles/s41579-019-0288-0

The critical next steps

The establishment of an independent SAB and a sound governing framework will be key to ensure the AMR Action Fund's effectiveness in delivering results.

The SAB will have an essential role, as it will evaluate the clinical utility of the different candidates based on a set of pre-defined criteria, taking into account the innovation and next generation approaches that are in the pipeline. To properly fulfil its mission, it is paramount that the SAB be composed of independent scientists, selected from diverse profiles (epidemiologists, clinicians, microbiologists, etc.), representing different schools of thoughts with an appreciation of global and regional AMR challenges.

On governance, the BEAM Alliance welcomes the added value that can result from enhanced collaboration between pharmaceutical companies, given the know-how they can bring to late-stage development, manufacturing and distribution of antimicrobials. A sound governance framework, however, must foster these relationships whilst protecting the interests of small biotech companies and their early-stage investors.

Beyond funding: a call for PULL incentives

The BEAM Alliance hopes that initiatives like the AMR Action Fund can rekindle interest and confidence among other investors and bring additional funding opportunities, including for earlier stage projects, in what has been a neglected area in research and development. Moreover, we hope that such initiatives further encourage governments and policy makers to evaluate options to review PULL incentives for the development of new antibiotics.

In addition to increased funding, the repopulation of the AMR investment field would require systemic and lasting change in market conditions, with a view toward enabling a sustainable pipeline of antibiotics. BEAM will continue to advocate for better market perspectives, which are a matter of utmost urgency to those that develop antibacterial products and those that invest in them.

The ambition and 10-year goal of the AMR Action Fund must be matched by a commercial ecosystem that is supportive of innovation in the field, so that the antibacterial drugs developed as a result of this funding can be truly viable from a market as well as scientific and clinical perspective.

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