



# BEAM Alliance and global partners call for urgent action on new reimbursement models for life-saving antibiotics

***This paper is being supported by the following organisations and individuals:***

- [BEAM Alliance](#)
- [Antimicrobials Working Group \(AWG\)](#)
- [Biotechnology Innovation Organization \(BIO\)](#)
- [Global Antibiotic Research and Development Partnership \(GARDP\)](#)
- [International Council of Biotech Associations \(ICBA\)](#)
- [International Federation of Pharmaceutical Manufacturers & Associations \(IFPMA\)](#)
- [Novo Holdings REPAIR Impact Fund](#)
- [Pfizer Inc.](#)
- [Working to Fight AMR](#)
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**The COVID-19 pandemic has turned our world upside-down, but antimicrobial resistance (AMR), already at a pre-pandemic stage, could soon be even more devastating.**

The coronavirus (COVID-19) pandemic is having a devastating effect on global health and an unprecedented impact on the global economy.

As the world struggles with the challenges brought by this pandemic, the threat of the next one is already looming in the form of AMR. AMR is already responsible for an estimated 750,000 deaths worldwide on an annual basis. In some countries, 35% of human infections are caused by bacteria that are resistant to commonly used antibiotics. Furthermore, in some low- and middle-income nations, resistance rates are as high as 80-90% for certain antibiotic-bacterium combinations. It has been estimated that by 2050 mortality attributable to AMR could reach 10 million deaths globally per year.

### **Significant PUSH initiatives are in place**

The AMR crisis has been comprehensively described and analysed since a landmark report in 2016 - the Review on Antimicrobial Resistance from the UK<sup>1</sup> - which included policy guidance on how to prevent AMR from becoming a global phenomenon. Since then, several other analyses have been conducted with similar proposals and conclusions.

Some actions have been taken, with varying degrees of success, to increase the odds of successfully combatting the AMR crisis:

- The WHO designated priority pathogens, drafted Target Product Profiles<sup>2</sup>, and worked with member states on AMR action plans.
- The Global Antibiotic Research and Development Partnership (GARDP)<sup>3</sup> was formed as a non-profit organization to work on innovation in, and global access to, urgently needed novel antibiotics.
- Responding to the need for more R&D incentives and funding (so-called “PUSH” incentives), the global non-profit partnership CARB-X<sup>4</sup> was formed to accelerate antibacterial research. At the European Union (EU) level, research funding was made available by both the Member States and the EU (e.g. Innovative Medicines Initiative or InnovFin) to support research and innovation for new drugs. This led to a multitude of early stage innovations, and thus novel product candidates. With the help of such PUSH funding and a few remaining investors, small and medium-sized enterprises (SMEs) - who hold today's AMR global product pipeline - have delivered promising preclinical candidates<sup>5</sup>.
- More than 20 leading pharmaceutical companies have just launched a ground-breaking collective venture to invest nearly \$1 billion through a new AMR Action Fund<sup>6</sup> that aims

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<sup>1</sup> <https://amr-review.org/>

<sup>2</sup> The WHO defines Target Product Profiles as an outline of the desired ‘profile’ or characteristics of a target product that is aimed at a particular disease or diseases.

<sup>3</sup> <https://gardp.org/>

<sup>4</sup> <https://carb-x.org/>

<sup>5</sup> [https://www.who.int/research-observatory/monitoring/processes/antibacterial\\_products\\_preclinical/en/](https://www.who.int/research-observatory/monitoring/processes/antibacterial_products_preclinical/en/)

<sup>6</sup> <https://amractionfund.com/>

to bring 2 to 4 new antibiotics to patients by the end of the decade. The concept of the AMR Action Fund was developed in collaboration with the WHO, the European Investment Bank (EIB), and the Wellcome Trust.

Whilst these initiatives represent a helpful step in the right direction, they do not encompass the whole spectrum of actions necessary to create a viable economic environment in which companies developing lifesaving antibiotics can survive and prosper.

### **Europe is at risk of not having access to the newest life-saving medicines**

Because new antibiotics are (appropriately) held in reserve, developers of new medicines have struggled financially or have gone bankrupt. The remaining companies are at this point focusing their regulatory and commercial efforts on the U.S. The flow of new antibiotics to Europe could come to an abrupt halt as soon as this year.

The BEAM Alliance and the co-signatories of this paper urge the EU and its Member States to urgently act and fix the broken economics around investment into the development and commercialization of antimicrobials.

This needs to be done in a coordinated way, as exemplified by NGOs and businesses that are taking the AMR problem seriously and implementing significant funding opportunities to offset the costs associated with antibiotic development, as noted. After years of discussions, it is now time for governments to commit to rapid action of a similar scale to the industrial and governmental response to the COVID-19 pandemic. This is surely a similar wake-up call to fix the broken economics surrounding new antibiotics and to avoid a world without new and effective life-saving antibiotics. The emerging global issue of AMR, a slower but ultimately more dangerous pandemic, is no exception.

### **Recommended follow-up actions to fight the AMR threat**

The COVID-19 crisis has reminded us that developing drugs or vaccines takes time and must be anticipated. In order to ensure effective new products against AMR reach patients in Europe over the next critical years, significant efforts are urgently needed to establish a pan-European strategy to incentivize innovation in AMR product development and commercialization.

**Against this background, the signatories of this paper call for the design and implementation of new economic incentive models (“PULL”) for AMR products, and call on:**

*The European Commission to:*

- Propose a new PULL incentive framework, as part of the upcoming EU Pharmaceutical Strategy, to address critical factors leading to commercial non-viability of launching novel life-saving antimicrobials.
- Stimulate the exchange of information and best practices between Member States.
- Deliver concrete guidance to Member States regarding the magnitude of incentives required, based on the Member States’ GDP share.

*EU Member States to:*

- Champion, as part of the upcoming EU Pharmaceutical Strategy, the introduction of a new EU legislative framework to enable and encourage the development and commercial introduction of novel antibiotics, and adopt it as soon as possible.
- Take advantage of the recently released mapping of incentives by the Global AMR Hub<sup>7</sup> and of the coordination work performed by the EU-JAMRAI Joint Action<sup>8</sup> to implement HTA and reimbursement reforms in their respective National Action Plans, in a similar way to what the UK and Sweden have already done.
- Setup and implement their own model, compatible with their existing national requirements and including a set of appropriate guardrails, that would allow testing of alternate features:
  - Reimbursement should capture the societal benefit of AMR products, while warranting best medical care.
  - Sustainable use of and access to antibiotics should be aligned with appropriate market incentives covering minimal reimbursement targets. Such a delinked revenue model is paramount for the sector.
  - Appropriate tools, like Market Entry Rewards, Subscription Agreements or Transferable Exclusivity Vouchers have been proposed and discussed<sup>9</sup>. Countries should decide on the best-fitting option to their current Health Technology Assessment regulations, and implement this at national or European level.

*Members of the European Parliament to:*

- Drive Europe to play a leading role in the fight against AMR, and ensure the survival of this strategic industrial ecosystem, composed mainly of SMEs.
- Support, as part of the upcoming EU Pharmaceutical Strategy for Europe, the introduction of a new EU legislative framework to provide appropriate incentives for the development of novel antibiotics, and adopt it as soon as possible.
- Advocate for the necessary changes outlined above to happen as soon as possible in their respective Member State.

AMR is an emerging global crisis, already recognized at several G20 summits as an urgent issue requiring action. In addition to the EU we also call on non-EU governments to take similar action and to adopt adequate reimbursement models for AMR products, besides implementing AMR Action Plans under the One Health initiative from WHO.

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<sup>7</sup> <https://dashboard.globalamrhub.org/reports/incentives/incentives>

<sup>8</sup> <https://eu-jamrai.eu/>

<sup>9</sup> <https://beam-alliance.eu/wp-content/uploads/2019/11/the-beam-pull-memo.pdf>