Reflection paper on the EU Pharmaceutical Strategy

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.

January 26th, 2021
The BEAM Alliance welcomes the European Commission’s Pharmaceutical Strategy, which recognises the development of novel antimicrobials as a prime example of an unmet medical need and proposes important measures to address the rising threat of antimicrobial resistance (AMR), which requires urgent action. We count on the Commission to foster short-term solutions in parallel to long-term incentive reforms, and to consider the specific challenges faced by European small and medium-sized enterprises (SMEs) in the field. Europe’s preparedness for the next global health crisis may be tested sooner than its legislative pace can keep up with.

As stated in the European Commission’s Pharmaceutical Strategy, the growing resistance of pathogens, such as bacteria, to antimicrobials has rendered it alarmingly common for bacterial infections not to respond to existing treatments. In Europe, AMR accounts for more than 33,000 deaths every year. If no action is taken, the World Health Organization (WHO) predicts that it will cause 10 million deaths worldwide each year by 2050, i.e. more than cancer and diabetes combined.

Representing over 60 European small and medium-sized biotech companies carrying out research and development (R&D) projects for prevention, diagnosis, and cure of microbial infections, the BEAM Alliance thus welcomes the Pharmaceutical Strategy, which recognises the development of novel antimicrobials as a prime example of an unmet medical need.

As acknowledged in the Strategy, the development of new antibiotics is hampered by a market failure. The measures to reduce the excessive and inappropriate use of antimicrobials, while essential to preserving their effectiveness, have the inadvertent consequence of discouraging investments.

We agree with the European Commission that new business approaches are needed to address this issue. In developing solutions to tackle AMR, our work aims to future-proof medicine as we know it. Nonetheless, the development of new antimicrobial solutions requires incentives that are not just sales-based, but outcome-oriented and partly delinked from market uptake. We call on the European Commission to take this into account when exploring new types of incentives for innovative antimicrobials as part of the review of the pharmaceutical legislation in 2022.

While incentive reforms are crucial to maintain a sustainable pipeline, we emphasise that faster solutions are urgently needed. Indeed, it takes 10 to 15 years to develop a new antimicrobial, meaning that the choices we make today will directly determine the options we have tomorrow.

We therefore welcome the proposals made in the Pharmaceutical Strategy to promote investment, and coordinate research, development, manufacturing, deployment and use for novel antibiotics as part of the new EU Health Emergency Response Authority (HERA) by 2021, prior to the start of the authority’s operations preparatory action.

Similarly, we also very much support the Commission’s commitment to pilot innovative approaches to EU R&D and public procurement for novel antimicrobials in 2021. We strongly hope that such initiatives can effectively improve “pull incentives” in the short term. We also hope these approaches will embrace a broad definition of antimicrobials, including non-traditional approaches and diagnosis, to truly capture the profile of current pipeline’s assets.

When designing and implementing the above-mentioned initiatives, it is paramount that the European Commission takes into consideration the role of and challenges faced by SMEs. Despite being the main players in AMR innovation today (as most large corporations have withdrawn from antibiotics R&D due to low returns on investment), SMEs are struggling financially to advance

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their AMR development programmes and are prevented from generating revenue due to inadequate incentive frameworks.

The BEAM Alliance stands ready to provide all necessary input to support the Commission in finding innovative solutions that can be deployed in the short term, and to contribute to the debates on systemic, long-term reforms.

A future-proof regulatory framework is one that not only ensures preparedness for future crises, but that also has the means of preventing them. We count on the European Commission, the Member States, and the European Parliament not to miss the opportunity presented in the Pharmaceutical Strategy to change course in time. Our chance to avoid the next global health crisis and to save a whole ecosystem of European SMEs depends on it.

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