

## Joint Statement on Antimicrobial Resistance

### Executive Summary

Antimicrobial resistance, also known as AMR, is a major public health threat. The estimated burden of deaths from drug resistant infections is calculated to reach 10 million lives every year by 2050. AMR is now a critical global agenda item that requires proactive and coordinated action, as recognized by in the [WHO Global Action Plan](#), the [UN High Level Meeting declaration](#), the G7 and G20 meetings, and the European Commission's [Roadmap on a "One Health" Approach to AMR](#). We believe this is an area where the EU can and should take a leading role by proposing concrete and innovative solutions to benefit patients worldwide.

Action is required across all sectors and stakeholders, including national governments, the pharmaceutical and medical diagnostics industries, academia, civil society organisations, healthcare providers, and patients in order to find solutions. The European research-based pharmaceutical industry is determined to play its role in tackling this issue and reaffirms its commitment to a comprehensive, **multi-sectoral approach to address AMR and foster innovative solutions**. Our industry's commitment is embodied in the [Davos Declaration](#) of January 2016, and the subsequent [Industry Roadmap](#) from September 2016, which lay out proactive actions and commitments EFPIA members are taking to support access and ensure rational use of our medicines and diagnostics, reduce the development of antimicrobial resistance, as well as invest in research and development to meet public health needs. In addition, through the recently launched [AMR Alliance](#), we are partnering with generic and diagnostic companies to support a comprehensive approach and measure industry's progress to curb AMR.

We strongly support increased multi-stakeholder cooperation at EU level and believe that the European Commission should have a central role in facilitating a debate among all actors, including Member State governments, to define a comprehensive approach to combat AMR. We believe that the EU and Member States have a critical role to help avert this looming public health crisis by:

- Creating an environment where stakeholders can collaborate to address the challenge at national and EU level
- Closely collaborating to ensure the development and implementation of national AMR Action Plans that include a holistic approach to monitoring and surveillance and by encouraging the use of alternative treatment and prevention options including vaccines
- Putting in place the right mechanisms to stimulate the development of new antibiotics and vaccines
- Adapting the regulatory framework to enable efficient pathways for drug development in this area
- Addressing environmental concerns
- Maintaining international attention to the issue.



## 1. Supporting Member State National Actions against AMR

We strongly welcome the European Commission's commitment to support Member States in developing and implementing comprehensive national strategies against AMR, as highlighted in the [Evaluation of its first Action Plan](#). Although many countries have specific measures against AMR in place or are committed to developing national plans to combat AMR, there are considerable disparities in their level of ambition, as well as in the resources devoted to their implementation. **The EU should encourage Member States to be bold and to implement measures preventing AMR** that are identified through best practice sharing and benchmarking. One concrete means to achieve this is to take advantage of existing Joint Actions (e.g. Joint Action on AMR & HAI, Joint Action on Vaccination) and to integrate considerations linked to AMR into the overall measures coming out of these Joint Actions.

Moreover, we strongly support the need for a **holistic approach to the monitoring and surveillance of AMR**. Member States should strengthen prevention options by integrating vaccination planning into EU and national plans to be developed for the fight against AMR, as mentioned in the [Vaccines Europe position paper](#); share best practices, and optimise data collection measuring antibiotics usage and resistance. We would thus welcome clear actions, targets and measures concerning prevention and surveillance in the second Commission Action Plan on AMR and in national Action Plans. We also believe the EU institutions can help progress in these areas in a more formalised way than it has currently done, for instance by asking ECDC to conduct regular monitoring of and reporting on the different prevention methods and by fostering more best practice exchange<sup>1</sup>.

Finally, industry firmly believes that **private sector engagement in the context of the 'One Health Network' is crucial**, as the private sector continues to be an important interlocutor in the various initiatives at national and global level on AMR.

## 2. Putting in place the right mechanisms to foster the development of new antibiotics

Pharmaceutical incentives and rewards are the foundations on which innovation is built. Overall, the European legislative framework provides effective and structural long-term incentives for pharmaceutical innovation. These incentives work in the context of antibiotics as they do in other therapy areas, by driving research and development (R&D) and by supporting innovation that could improve or even cure many diseases and change the lives of patients. In the current debate triggered by the European Commission's study of intellectual property (IP) incentives in the pharmaceutical sector, it is essential to recall the instrumental role of IP for R&D also in the context of antibiotic research.

In the field of antibiotics, however, the traditional market logic is in itself ill-equipped to incentivize antimicrobial innovation sustainably. Incentives are needed across the lifecycle of novel antibiotics and vaccines to stimulate R&D investment and address the lack of financial return for these products. In recent years, leaders in both the public and private sectors have therefore called for new economic models and market interventions to encourage sustainable investment in R&D in this area and improve predictability of the demand. The pharmaceutical industry continues

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<sup>1</sup> As highlighted in Dr. Ammon's address to the ENVI Committee in the European Parliament, 31 January 2017



to look for tailored, effective and long-term solutions developed in partnership to foster a fertile environment for R&D and ensure that the growth of resistance is sustainably managed and controlled.

### *Prioritisation and infrastructure*

We recognize the need for prioritization to efficiently incentivize R&D and direct research investment to areas of highest unmet medical need. Guidance on where to focus efforts to address unmet medical needs in antimicrobial research is required, and in this respect, we welcome efforts such as the WHO priority pathogens list. Agreed upon priority pathogens would be of important value to the development of antibiotics as well as other key tools to combat AMR, such as vaccines and diagnostics. We also believe that the European Commission should develop a European priority pathogens list, aligned with the WHO list, following a discussion with all relevant sector stakeholders, including the private sector. This list would help determine research priorities and stimulate R&D in Europe, if coupled to appropriate pull mechanisms, and ensure that the EU continues to contribute to globally relevant solutions.

### *Continuing the work done on push mechanisms*

A relatively significant amount of attention has been placed on the development of “push” mechanisms through e.g. research grants, or establishing public–private partnerships for sharing R&D. They can contribute to the advancement of knowledge and strengthening the discovery of new molecules and, to a lesser extent, to the development of new treatment and prevention options. Governments and other funding agencies should continue to provide funding dedicated to supporting pre-competitive R&D of novel antimicrobial compounds. The mechanisms for accessing such funding should be efficient, with non-burdensome reporting requirements. In this respect, projects such as those initiated under IMI, the European Commission/EFPIA public-private partnership are valuable and should be continued.

### *Accelerating progress on pull mechanisms*

Complementary to these “push” mechanisms, and also of critical importance, are “pull” mechanisms, which reward the successful development of new antimicrobial medicines. The unique challenges of AMR necessitate that new antibiotics should be used only to the extent that it is medically necessary and appropriate. Therefore, we are in a unique setting where specific pull mechanisms are needed to help provide sufficient return on investments and improve predictability of the demand. Otherwise, there is a lack of incentives for pharmaceutical companies to take on the necessary risk and uncertainty that comes with the development of new antibiotics and vaccines. The fact that there are – despite a large amount of push support – still few antibiotics that have reached the market shows that pull mechanisms need to become a priority.

The [Council Conclusions of 17 June 2016](#) “On the next steps under a One Health approach to combat antimicrobial resistance” call on Member States and the European Commission to actively engage in initiatives and proposals to implement new business models to bring new antibiotics to the market. Ongoing efforts at global level, European and national levels offer several opportunities to operationalize novel economic models in cooperation with governments. Agreement on how novel economic incentives would be funded and implemented are a critical gap and the pharmaceutical



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industry is engaging with stakeholders around the world to explore viable novel incentive mechanisms that both:

- Reward innovation earlier in the product life cycle, while increasing predictability, with the objective to help ensure that several treatment options are available to society to combat resistant infections.
- Reduce the proportion of manufacturer revenue derived from antibiotic sales volume (often called “de-linked” or “partially de-linked” models referring to different options for the interaction between revenue and volume) while adequately incentivizing development, which is especially important for antibiotics that are likely to be used rarely or to be reserved for late-line use.

Industry is reflecting on proposals for such incentives, as highlighted in the [IFPMA Position Paper](#) describing a number of proposed models to incentivize antimicrobial R&D. The IMI DRIVE-AB project is also looking into a number of potential options.

We are keen to engage with governments and the European Commission on the design of these models. At the same time, urgent action is needed. Investment decisions on R&D for tomorrow’s novel antibiotics are being taken today. While novel incentive mechanisms are being explored, we must address current reimbursement challenges for novel antibiotics that undermine confidence in R&D for future antibiotics. The establishment of new regimes for the pricing and reimbursement for antibiotics and other counter-measures is a member state competence. Nevertheless, it is the collective effort that will make the difference. The EU should ensure the importance of pull mechanisms continues to be recognized at global level and to consider using EU instruments to implement robust “pull mechanisms”.

Specifically for vaccines being developed for use in large populations in view of reducing the need for antibiotics and therefore the risk of antimicrobial resistance, an important pull incentive will be to remove uncertainty around market potential through Advance Market Commitments in developing countries and an early commitment from the National Recommending bodies and payers in developed countries. There may be specific cases, e.g. vaccines used to prevent nosocomial infections in a targeted population, where other incentives may be applicable.

Overall, industry supports a **multi-dimensional approach to “push” and “pull” incentives**. We maintain that only a robust approach to incentive models and programs can sufficiently, and efficiently, address current gaps in this area. We urge the European Commission to facilitate a debate among stakeholders ranging from Member States to industry, to share ideas and best practices.

### 3. Adapting the regulatory framework for the development of new antibiotics

It is of fundamental importance that there be a regulatory framework that enables efficient pathways for drug development in this area. We welcome the clarity and guidance provided by the European Medicines Agency (EMA) over the past few years regarding the development of antibacterial drugs<sup>2</sup>. We are also encouraged by the outcome of the [tripartite meeting](#) held in June

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<sup>2</sup> For reference in the context of the EFPIA discussion: The EMA published several guidance documents, including: [Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections](#); [Addendum to the guideline on the](#)



2017 between the EMA, FDA and PMDA to align regulatory approaches for the evaluation of antibacterial agents. We firmly agree that there is benefit in further convergence of the data requirements for the approval of antibacterial agents and believe such efforts will have a positive impact on antibiotic innovation and global access to these life-saving medicines.

**Dialogue between innovators and regulatory authorities should be encouraged in order to identify and create the necessary regulatory frameworks** to support the development of innovative treatments and prophylactic strategies. We believe there are a number of areas, for both vaccines and medicines, where further progress could be made in enhancing regulatory pathways. Specifically for vaccines, a multi-stakeholder reflection would help identify in which cases the regulatory framework should be adapted to speed up the access to vaccines targeting nosocomial pathogens. These vaccines that will be used in targeted populations may fall under an accelerated regulatory assessment.

#### 4. Addressing the concerns on the environmental impact of antibiotics

The pharmaceutical industry believes that environmental protection contributes to ensuring the health and safety of future generations. There are various ways in which Active pharmaceutical ingredients (APIs) can enter the environment throughout the lifecycle of a medicine, whether it is via natural excretion, improper disposal, or effluents from manufacturing facilities. Industry is committed to measures to reduce environmental impact from production of pharmaceuticals, including antibiotics. The pharmaceutical industry have initiated several health-based commitments and is working through the AMR Alliance, the Pharmaceutical Supply Chain Initiative ([PSCI](#)) and the [Eco-Pharmaco-Stewardship \(EPS\) initiative](#) to come up with concrete solutions. According to the O'Neill report, 30-40% of antibiotics are misused or wrongly diagnosed. More effective diagnosis and targeted patient use is important from a clinical perspective, but it also will have the highest impact on reducing the environmental burden of antibiotics. Environmental surveillance will help track this. Industry remains open to dialogue between all stakeholders responsible for the environment to elaborate an environmental monitoring approach. In addition, industry together with other stakeholders, is working on tackling the improper disposal of antibiotics, through the [medsdisposal](#) campaign.

#### Concluding Remarks

AMR is a critical global health threat requiring proactive, coordinated action to ensure a sustained response and the pharmaceutical industry remains committed to advance its work in this area and to cooperate towards the shared goal of combating antimicrobial resistance. We call upon governments, multilateral institutions, the private sector and civil society to follow through on the momentum provided by the UN, G7, G20 and the 67 national AMR action plans sponsored by governments around the world to implement concrete policy actions.

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[evaluation of medicinal products indicated for treatment of bacterial infections](#); and the [Guideline on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products](#).



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