Committed to the fight against **Antimicrobial Resistance** (AMR)

Tackling antimicrobial resistance (AMR) requires the combined efforts of policy leaders, pharmaceutical companies, healthcare professionals and patients. As a leading global provider of anti-infective medicines and vaccines, Pfizer is at the forefront of providing solutions that protect from infectious disease. In order for this to be sustainable in the future, however, we need new business models and a predictable legislative framework in the EU to incentivise both early- and late-stage R&D in new treatments and vaccines. The next EU legislature can make this happen.

- AMR is the ability of microorganisms to resist antimicrobial treatments, especially antibiotics. In the last decades, this natural selection process has been exacerbated by human factors such as misuse of antimicrobials, and poor infection control practices.[1]

IN EUROPE, ABOUT
33.000
PEOPLE PER YEAR DIE
as a direct consequence of drug-resistant infections.[2]

AMR-RELATED HEALTHCARE COSTS AND PRODUCTIVITY LOSSES AMOUNT TO
€1.5 BN
ANNUALLY[3]

At the same time scientific, regulatory and financial hurdles make it increasingly challenging to develop new treatments to manage resistance. Without intervention, **by 2050 AMR could take 10 million lives per year globally**, more than cancer.[4]

- Tackling AMR requires the combined efforts of policy leaders, pharmaceutical companies, healthcare professionals and patients. The 2017 EU One Health Action Plan against AMR identified several key issues, and it is now time for concrete action from all public and private stakeholders.
- As a global leader in anti-infectives and vaccines, Pfizer is working closely with the infectious disease community to address AMR, including through:[5]
  - Active **stewardship** to help ensure patients receive the correct antibiotic only if needed and for the right duration;
  - AMR **surveillance** programmes for clinicians and public health officials to assess the nature and scale of emerging resistance, both locally and nationally;

ATLAS
PFIZER SPONSORS ONE OF THE LARGEST **AMR SURVEILLANCE PROGRAMMES** IN THE WORLD

MONITORING **RESISTANCE PATTERNS** IN MORE THAN **73 COUNTRIES**[6]

  - **Responsible manufacturing** practices that minimise the potential environmental impact related to the production of antibiotics;
  - **Diverse portfolio** of medicines and vaccines to treat and help prevent serious infections across the world.[7]

Key Policy Points

During the 2019-2024 legislature, we call on the EU and its Member States to:

1. Maintain a high political focus on the broader issue of AMR following a "One Health" approach;
2. Align AMR research funding, at national and EU-level, with the scale of the threat;
3. Implement comprehensive life-long vaccination programs, to help prevent infections and therefore reducing the need for antibiotic use;[9]
4. Design and implement, in collaboration with industry, a package of incentives at EU and national level to support research and development of additional anti-infectives and vaccines and strengthen a sustainable marketplace.

EU action needed to support R&D in new solutions against AMR

- The EU and its Member States have recognised the need for incentives and new business models to attract investment into R&D of new antibiotics, vaccines, alternatives, diagnostics, and stabilise the current marketplace. It is beyond time to move to concrete action.
- **So far, most efforts at EU level have been dedicated to "push" incentives aimed at de-risking basic research** (e.g. research grants or public-private partnerships like the Innovative Medicines Initiative, IMI) via cost-sharing mechanisms. These efforts have proven valuable and should certainly continue.
- In order to turn promising research into viable products, however, **we urge the European Commission to put forward a legislative proposal on AMR which would include, but not be limited to, robust "pull" mechanisms at EU level**, such as Transferable Exclusivity Extensions (TEE) or Market Entry Rewards (MER). Coupled with HTA and reimbursement reform at national level, these would form part of a comprehensive **package of incentives** that could effectively generate investments in both early- and late-stage R&D.

A package of incentives is needed to attract R&D investment into new solutions against AMR[8]

1 PUSH MECHANISMS

- Reduce the risk of early investment in antibiotic research.
- In addition, regulatory reform can help bring novel antimicrobials to market faster.

Examples: grants, R&D tax credits, regulatory reform (harmonization of regulatory requirements, abbreviated/facilitated pathways)

PRECLINICAL + EARLY CLINICAL PHASES

2 NOVEL PULL MECHANISMS

- Overall higher reward for successful innovation, particularly earlier in product life cycle when use is low and improves predictability.

Examples: transferable exclusivity extension, market entry rewards

AT LAUNCH: PHASES IMPACTED DEPEND ON THE VALUE OF THE PULL INCENTIVE

3 REIMBURSEMENT AND HTA REFORM

- Enable appropriate access and reflect the full range of societal value of novel antibiotics.

DURING THE LIFE CYCLE OF THE PRODUCT

ABOUT PFIZER - GLOBAL FIGURES

WE EMPLOY
> 92.000
COLLEAGUES

58
MANUFACTURING SITES

OUR PRODUCTS
reach patients in
> 170
COUNTRIES

WE INVESTED
$8.0bn
IN R&D IN 2018
(14,9% OF OUR REVENUE)

1. European Commission, *A European One Health Action Plan against Antimicrobial Resistance* (AMR), Brussels, June 2017. 2. Alessandro Cassini, MD et al., "Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis", *The Lancet*, Volume 19, Issue 1, P56-66, January, 2019. 3. ECDC/EMEA Joint Technical Report, *The bacterial challenge: time to react*, Stockholm, September 2009. 4. The Review on Antimicrobial Resistance, *Tackling Drug-Resistance Infections Globally: Final Report and Recommendations*, London, May 2016. 5. Pfizer's commitments to tackling AMR are embodied in the 2016 Davos Declaration, and the subsequent Industry Roadmap. We are leading members of the AMR Industry Alliance. 6. ATLAS data is accessible to the public, free of charge, including via a mobile app. 7. Pfizer Inc., *Patients at our center.* Pfizer 2018 Annual Review, New York City, 2019. 8. International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Policy Position on *Supporting sustainable investments in antimicrobial R&D*, Geneva, 2018.