

Taking action on AMR: Largest life sciences sector coalition shows leadership in R&D, appropriate use and access to antibiotics and responsible manufacturing

1 February 2022 (Geneva) – Today the AMR Industry Alliance released its latest Progress Report, reflecting on collective achievements from the life sciences industry to minimize the spread of antimicrobial resistance (AMR). Findings from the leading coalition of biotechnology, diagnostics, generic and large research-based pharmaceutical companies indicate continued focus and leadership from the life sciences sector. Industry is helping to shape a positive future outlook in the fight against AMR but continued cross-sector collaborations along with policy and regulatory changes toward a more sustainable marketplace are needed. The report's findings represent collective results from across Alliance membership on their current AMR activities related to research and science, access, appropriate use, and manufacturing and the environment. The report was conducted by RAND Europe.

Key findings include:

- There is continued funding in AMR from Alliance members, but investment levels are at risk. Since the previous survey period (2019-2020), at least USD\$1.8 billion have been invested annually. Nearly one-third of members reported that investment would decrease if market conditions did not improve.
- Incentives for R&D in antibiotics are critical for future investment. Almost three-quarters of Alliance members said they would increase investment if market conditions improved, particularly through sufficient novel pull incentives. These reward successful development and will be imperative to ensure market viability and enable sustainable investment into AMR R&D.
- An overwhelming majority of Alliance members are active in access and appropriate use activities. Four out of five (81%) surveyed companies reported being active in supporting access to AMR-relevant products and/or technologies. Implementation of appropriate use and stewardship activities were also reported as a major focus of companies, with 92% of R&D pharmaceutical companies, 89% of generics companies, and 80% of diagnostics companies having taken such actions.
- There is growing commitment and action on responsible manufacturing. An increasing number of Alliance members involved in manufacturing antibiotics (85%) are assessing their sites against the Alliance's Common Antibiotic Manufacturing Framework (CAMF), and 87% of products manufactured at Alliance members sites are meeting its science-based predicted no-effect concentrations (PNEC) targets.

"The AMR Industry Alliance stands out as the leading private sector coalition providing actionable solutions in the fight against AMR. As the Alliance enters its sixth year, through the Progress Report, we see the benefits of working in partnership across sectors and actors," said Thomas Cueni, Chair of the Alliance and Director General of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). "Antimicrobial resistance won't race across the world like COVID-19, but its effects will be devastating. Together, we need to think wisely about preparing against future pandemics, including silent ones like AMR. Leading companies in the life science sector are playing a principal role in harmonizing effective regulations, advancing market incentives, promoting appropriate use strategies, and continuing to strengthen multi-stakeholder collaborations."

New peer-reviewed <u>data</u> conducted by the Institute of Health Metrics and Evaluation (IHME) estimate the global burden associated with drug-resistant infections at 4.95 million deaths in 2019, with AMR directly causing 1.27 million deaths. These findings highlights that AMR's scale and threat is much larger than previously understood and therefore emphasise the urgency for taking action.



The Alliance encourages others in the life sciences sector to utilize the Progress Report as a tool to spur action and encourage greater collaboration in slowing the spread of AMR.

"The Progress Report calls out that the Alliance has made great strides across the AMR landscape but particularly toward responsible manufacturing, and we are proud of the improvements Alliance members have made," said Cueni. "These efforts to spur industry actions and move toward industry standards were recognized in this year's G7 Health Ministers Communique. This work is promising, yet we must continue the momentum."

Overall, the Progress Report reinforces ways in which Alliance members and the broader life sciences industry can contribute further to combating AMR. New and ongoing actions will include working with governments to strengthen pull incentives to ensure commercial viability of antimicrobial R&D, strengthening partnerships for access to diagnostics and antimicrobials, reducing substandard and falsified AMR-relevant products or technologies, increasing AMR surveillance data collection, aligning promotional activities with antimicrobial stewardship, working toward an industry manufacturing standard, and continuing to enhance compliance of sites with our manufacturing framework.

"AMR Industry Alliance members have made notable contributions to tackling the urgency of the AMR challenge on multiple fronts, including contributing to research and the development of novel AMR-relevant products and technologies, working to address access issues, supporting efforts to ensure the appropriate use of antimicrobials and the responsible manufacturing of antibiotics," said Sonja Marjanovic, Director, Healthcare Innovation, Industry and Policy, RAND Europe. "There are opportunities to further build on the progress made to date, through collaborative endeavours between and among industry, governments, intergovernmental organisations, not for profits, public sector researchers, healthcare professionals and payers – keeping patient needs at the center of all efforts."

The full AMR Industry Alliance Progress Report can be found here.

Summary of Key Findings:

Research and Science. Since the previous survey period (2019-2020), nearly half of Alliance members reported an increase in AMR-relevant R&D investment, and at least USD\$1.8 billion have been invested annually. Alliance members view new or improved pull incentives as a key factor to influence investments in AMR-relevant R&D and are committed to working with policymakers and actively engaging in advocacy efforts for improved pull and push incentives that could provide further stimulus for R&D and help create viable markets. In fact, 73% of surveyed Alliance members reported that they would increase investment levels in AMR-relevant R&D if market conditions improved.

Access. Top-line findings highlight that Alliance members are active in supporting access, with 81% of respondents reporting having developed comprehensive strategies to improve access to AMR-relevant products or technologies. Alliance member access-related activities covered diverse geographies, the majority of which are in low- and middle-income countries (LMICs). According to Alliance members, challenges related to appropriate pricing and reimbursement, a lack of timely and appropriate product registration and prescriber/payer behaviours that favour lower-cost older antimicrobials represent key barriers in industry efforts to enable wider access to AMR-relevant products and technologies.

Appropriate Use. Alliance members continue to engage in activities to promote good stewardship. The report found that 83% of large R&D biopharmaceutical companies and 80% of diagnostics companies have appropriate-use and stewardship strategies or plans for AMR-relevant products and/or technologies. While Alliance members are very active in appropriate-use and stewardship education and awareness (88% report such programs), just half (51%) report collecting and/or sharing surveillance data. That said, over half (59%) of companies that collected surveillance data shared it externally as



part of their commitment to collaborative efforts to mitigate inappropriate use of antibiotics and vaccines and improve antimicrobial stewardship.

Manufacturing and the Environment. The Alliance's continued leadership to minimize AMR in the environment is proving fruitful. Top findings from the Progress Report indicate that the vast majority of products (88%) manufactured at sites owned by Alliance members with manufacturing operations have been assessed against PNEC targets and 87% of assessed antibiotic products meet these targets. Additionally, most (98%) antibiotic manufacturing sites owned by Alliance members either fully or partially met all CAMF requirements. However, there is room for improvement to ensure member company supplier sites are increasingly assessed against the CAMF and their products against PNEC targets.

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About the AMR Industry Alliance

The <u>AMR Industry Alliance</u> was formed in 2017. With approximately 100 life sciences companies and trade associations, it represents nearly one-third of the volume of sales and the majority of all novel products. Members have committed to report on activities they are undertaking in the areas of research & science, access to antibiotics and appropriate use of these, as well as responsible environmental manufacturing to tackle the rapid spread of antimicrobial resistance. If AMR remains unchecked, the annual death toll could climb from 700,000 each year to 10 million by 2050 and the economic impacts could be on par with those of the 2008 financial crisis. The AMR Industry Alliance ensures that signatories collectively deliver on the specific commitments made in the <u>Industry Declaration on AMR</u> and the <u>Roadmap for Progress on Combating AMR</u> and measures progress made in the fight against AMR.

About RAND Europe

RAND Europe is a not-for-profit policy research organisation which aims to improve policy and decision making through research and analysis. With offices in Cambridge (UK) and Brussels (Belgium), RAND Europe works with a wide range of government, industry, academic and third sector clients to conduct rigorous, impartial, and quality assured research. RAND Europe has an established focus on health and healthcare innovation including wide-ranging experience conducting research on AMR.