amr INDUSTRY ALLIANCE
UNITED AGAINST ANTIMICROBIAL RESISTANCE

THE 2023 AMR INDUSTRY ALLIANCE PROGRESS SURVEY:

Tackling antimicrobial resistance through contributions to research and science, access and appropriate use

RAND EUROPE

This report is based on independent, quality-assured research conducted by RAND Europe and funded by the AMR Industry Alliance.

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Context and Approach

Antimicrobial resistance (AMR) is a serious global public health concern, identified as one of the top three health threats by the Health Emergency Preparedness Authority (HERA) (European Commission 2022) and as one of the top ten global public health threats facing humanity by the World Health Organisation (WHO) (World Health Organisation 2021). Recent estimates suggest that 4.95 million deaths were associated with bacterial AMR alone in 2019 (Murray et al. 2022). In addition to health-related impacts on populations, AMR also has significant economic impacts, with some estimates suggesting that AMR could cost from US$300bn to USD 1 trillion annually at a global level by 2050 (Dadgostar 2019).

Addressing AMR is, therefore, a public health priority, requiring global collaboration between diverse actors in the public, private and not-for-profit sectors. The life sciences industry needs to be a crucial partner in the effort. In this context, the AMR Industry Alliance (AMRIA) was established in 2017 to provide sustainable solutions to curb AMR (AMR Industry Alliance 2023), bringing together 77 leading biopharmaceutical (n=12), diagnostic (n=4), biotechnology (n=51) and generics (n=10) companies,[1] as well as ten industry associations, to harness the know-how, resources and infrastructure of industry to help with this effort. It does so by focusing on contributions to four key areas of activity, each representing a crucial part of the AMR puzzle: research and science, access, appropriate use and responsible antibiotic manufacturing of antimicrobials.

This report provides a snapshot of AMRIA's efforts to deliver on their commitments to tackle the rise of AMR across three pillars of Alliance activities: 'research and science', 'access' and 'appropriate use' (see Annex A1 for further details). Progress with activities related to responsible manufacturing and the environment is reported on in a separate report (see https://www.amrindustryalliance.org/mediaroom/amr-industry-alliance-contributions-to-responsible-antibiotic-manufacturing/).

This is the fourth iteration of the Alliance's biannual progress reporting. It is based on a survey of Alliance members designed, administered and analysed by the not-for-profit research institute RAND Europe. The survey (see Annex A2) examines AMR-relevant activities of Alliance members between 1 April 2021 and 31 March 2023. One representative from each member company was asked to complete the survey.

Of 77 members of AMRIA (by 'member', we are referring to a member company), a total of 43 completed the survey, yielding an overall response rate of 56%. It is worth noting that the response rate was 100% for three of the four sectors. More specifically, all research and development (R&D) pharma sector (12 of 12), generics sector (10 of 10) and diagnostics sector (4 of 4) Alliance member companies and 33% (17 of 51) of biotech/small-and-medium-sized-enterprises (SMEs) sector members responded to the survey. All did so with informed consent.

Although the report captures a diversity of member contributions to tackling AMR and reflects on future considerations, there are some caveats to keep in mind when interpreting the findings. Given the small number of companies in the Alliance from this sector, we advise some caution regarding interpretation related to the diagnostics sector. It is also worth bearing in mind that approximately a third of all AMRIA biotech members responded to the survey; hence, their responses may not entirely represent the Alliance's overall biotech membership. Finally, although questions were developed with some built-in quality-control checks, auditing the data was outside the scope of this work.

This report was authored by Dr Frances Wu, Mr Daniel Lee and Dr Sonja Marjanovic at RAND Europe.

A list of Alliance members invited to participate in the survey is provided below.

TABLE 1. AMR INDUSTRY ALLIANCE MEMBERS (*DENOTES COMPANIES THAT PARTICIPATED IN THE SURVEY)

LARGE R&D BIOPHARMACEUTICALS

- * Boehringer Ingelheim
- * F. Hoffmann-La Roche AG.
- * GlaxoSmithKline plc
- * Johnson & Johnson
- * Menarini Ricerche
- * Merck KGaA
- * MSD (known as Merck and Co. Inc. in the US and Canada)
- * Otsuka
- * Pfizer Inc.
- * Sanofi S.A.
- * Shionogi & Co. Ltd.
- * Sumitomo

BIOTECHNOLOGY/SMEs

- * Aequor Inc.
- AiCuris Anti-infective Cures GmbH
- Allecra Therapeutics
- Alphanosos
- * Antabio
- Aurobac Therapeutics
- * Athlone Laboratories
- BioFilm Control
- * BioVersys AG
- * Blacksmith Medicines
- * Bugworks Research
- * Clarametyx
- Combioxin
- Contrafect
- Curza
- * Destiny Pharma Ltd.
- Eligo Bioscience
- Fastinov
- * Fedora Pharmaceuticals Inc.
- Helperby Therapeutics plc
- * HYpharm GmbH
- Innoviva
- * Infex Therapeutics
- iNtRON Biotechnology Inc.
- * Locus
- Meiji Seika Pharma Co.

Microbion Corporation
Moderna
Mutabilis
Nabriva Therapeutics AG
NAICONS
Northern Antibiotics Ltd.
Nosopharm
NovaBiotics
Oragenics, Inc.
* Paratek
* Peptilogics Inc.
Phare Bio
Phereceydes Pharma (France)
Pherecydes Pharma (US)
* QureTech Bio AB
Scynexis
SetLance
Soligenix
Spero Therapeutics LLC
Spexis AG
Summit Therapeutics
* TAXISpharma
Union Therapuetics
* Venatorx Pharmaceuticals Inc.
VibioSphen

DIAGNOSTICS

* BD
* bioMérieux SA
* Cepheid
* MeMed

GENERICS

* Aurobindo
* Centrient Pharmaceuticals
* Cipla
* Fresenius Kabi
* Sandoz
* Recipharm
* Teva Pharmaceuticals, Ltd.
* Venus Remedies
* Viatris
* Xellia

AMRIA contributions to tackling AMR through research and science

Over the last decade, the profile of AMR as a public health challenge has been significantly raised amongst decision makers globally (Anderson et al. 2023). However, the pipeline of novel antimicrobials remains insufficient relative to the degree of need due to a range of scientific, technological, regulatory and economic challenges (Anderson et al. 2023). Without investments in research and development, the supply of promising diagnostics, antimicrobials, vaccines and other innovative solutions will likely stagnate (AMR Industry Alliance 2023).

AMRIA focuses on responding to this challenge and contributing to R&D for innovative diagnostics and new technologies, treatments and vaccines that can help combat AMR. Its members are also committed to discussions that can evolve the policy landscape to support sustainable investment and incentives for R&D and to working in partnership with public and private stakeholders to share relevant non-proprietary data to help advance public health goals (AMR Industry Alliance 2023).

Box 1 below highlights key contributions of Alliance members to tackling AMR through research and science between April 2021 and 31 March 2023 (covering the period since the last AMRIA progress survey). Further detail is provided in the narrative that follows.

BOX 1. **RESEARCH AND SCIENCE HIGHLIGHTS: KEY INSIGHTS ON PROGRESS**

Alliance members made significant contributions to the fight against AMR by investing in AMR-relevant R&D. Overall, 34 companies made investments to the value of approximately US$1.96–2.04bn annually in the 2021 and 2022 fiscal years. Compared to fiscal year 2020, most R&D-active surveyed companies in 2021 either increased investments substantially (47%) or maintained similar investment levels (38%). Investments supported R&D on diverse AMR-relevant products and technologies, with investments in AMR-relevant vaccines, antibiotics and diagnostic platforms being the most common.

All surveyed R&D active companies engaged in collaborative R&D-related activities, reflecting Alliance members' commitment to working together in the fight against AMR. The most common partnerships were with other private sector organisations (85%), but over two-thirds of responding R&D active companies also reported partnerships with country-level government bodies and academic institutions (68%). Over half (53%) collaborated with other types of organisations, e.g. not-for-profits, public-private partnerships and international AMR-focused initiatives or networks.

Collaboration in R&D includes sharing data and information related to AMR-relevant R&D. The majority of surveyed R&D active companies (82%) facilitated data sharing and/or exchange of information, but the types of data and information shared varied across survey respondents. This included data related to clinical trial results, epidemiology and/or surveillance, new compound leads, clinical trial design and new drug targets. Although commercial sensitivities need to be borne in mind, there is an opportunity to enhance data and information sharing in some key areas to help bolster an efficient R&D ecosystem, such as clinical trial results and epidemiological and surveillance data.

The financial investments made into R&D by Alliance members are an important part of global efforts to tackle AMR. However, Alliance members experienced significant challenges affecting their decisions on whether and how much to invest. The top two key challenges identified by 82% of R&D active companies were market viability concerns and a lack of appropriate pull incentives/instruments. Nearly three quarters also highlighted low historical sales volumes as a significant challenge (71%). Half or more flagged challenges related to a lack of appropriate push incentives such as external funding and tax credits (62%), the high cost of the regulatory approval process (56%,) and other company priorities (51%).

The investment climate for future industry-funded R&D efforts is uncertain. Close to three-quarters of surveyed R&D active companies indicated that they would increase investment if market conditions improve (71%), and similar numbers reported they would decrease investment if market conditions worsen (74%). Over two-thirds would maintain R&D investment levels if the market conditions remain unchanged.

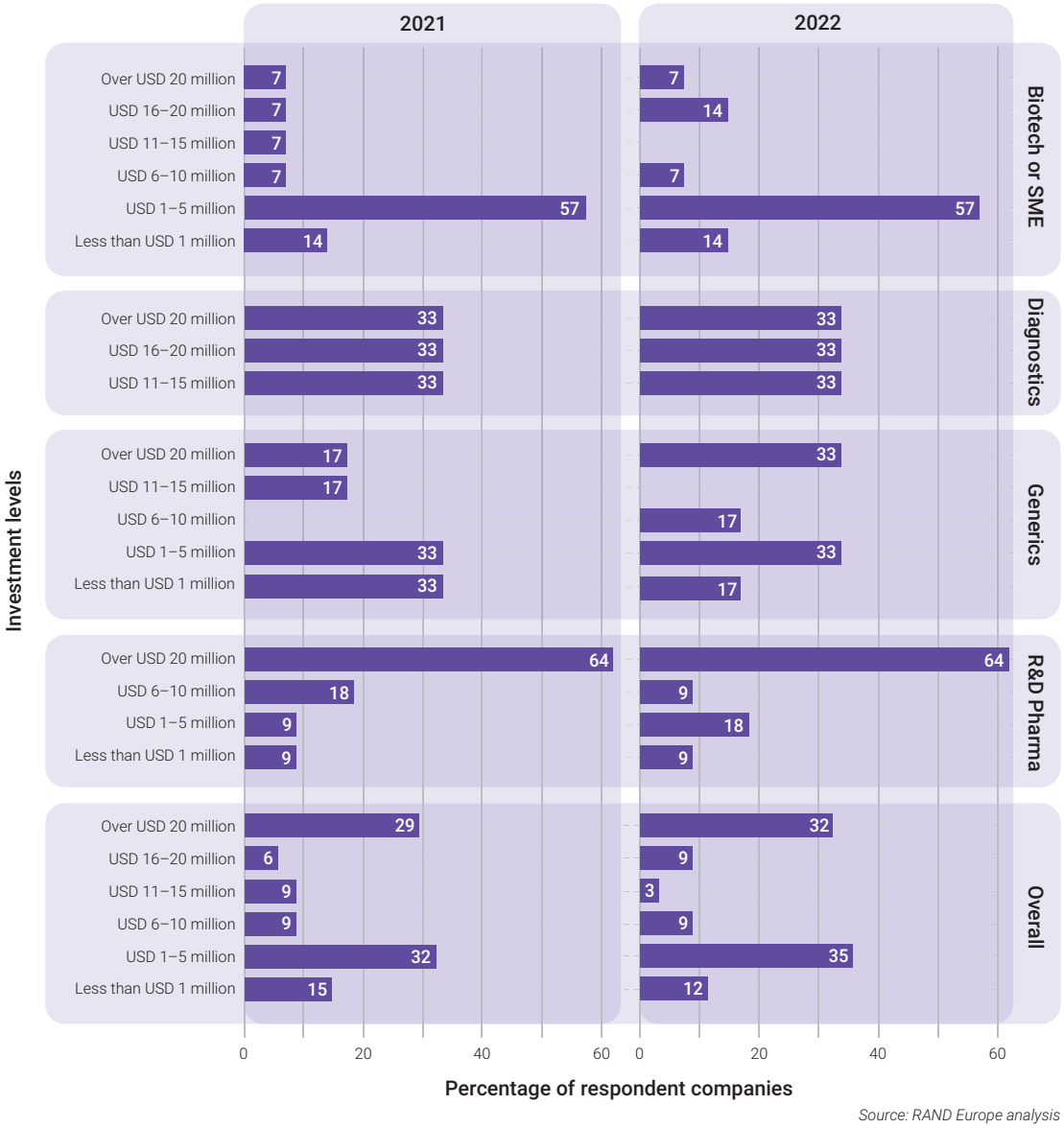
How much did Alliance members invest in AMR-relevant R&D?

The majority of surveyed Alliance members (79%, n=34) invested in R&D for AMR-relevant products and/or technologies during the survey timeframe. This includes 92% of R&D pharma companies responding to the survey (n=11), 82% of biotech/SMEs (n=14), 75% of diagnostics companies (n=3) and 60% of respondents from the generics sector (n=6). The comparatively lower number of R&D active generics companies is unsurprising because generics sector business models are by nature less R&D-focused.

During the survey timeframe, 34 Alliance member companies (44% of all Alliance members) **made significant investments in AMR-relevant R&D. These ranged from US$1,959–2,035m in Financial Year (FY) 2021 and, similarly, US$1,971–2,047m in FY 2022.**[2] These overall cumulative investment levels are slightly higher than those reported in the prior AMRIA progress report that covered FY 2019 and FY 2020 survey data and are attributable to an overall smaller number of companies.[3] Although direct comparisons of financial data across the years are inadvisable due to differences in the number and profile of responding companies, most R&D active surveyed companies (85%, n=29) reported that investments either increased substantially or stayed approximately the same in FY 2021, when compared to FY 2020 data in the prior reporting round.[4]

The financial value of AMR-relevant R&D investments varied across and within sectors, reflecting the diversity of Alliance members (see Figure 1). For example, R&D pharma, as expected, generally had higher levels of investment than other sectors, with 64% of responding R&D pharma companies that invested in R&D (7 of 11) investing over US$20m in FY 2021 and FY 2022.

FIGURE 1. INVESTMENT IN R&D FOR AMR-RELEVANT PRODUCTS AND/OR TECHNOLOGIES IN FY 2021 AND FY 2022 (N=34)



Source: RAND Europe analysis

What types of products did Alliance members invest in, and at what phases of development?

The AMR challenge is complex and dependent on research innovation in a range of areas that can help support wider efforts to ensure a sustainable supply of novel antimicrobials and vaccines, as well as diagnostics and other technologies that can enable appropriate prescribing and reduce emerging resistance risks. AMRIA is inclusive in its approach to considering what falls within the scope of products and technologies relevant to tackling AMR. For example, the Alliance recognises that some products and/or technologies that combat AMR in relation to bacterial and fungal infections may indirectly be related to AMR exacerbation due to an inability to distinguish between bacterial, fungal or viral infections. This can have an impact on inappropriate antimicrobial use and, as a result, AMR. Therefore, AMR-relevant vaccines (both anti-bacterial and those that impact the inappropriate use of antibiotics, including vaccines for viruses such as influenza, COVID-19, respiratory syncytial virus [RSV] and other respiratory infections) were considered in scope for companies responding to the survey. Similarly, diagnostics tests that help distinguish between viral and bacterial infections with a clear link to AMR were also in scope.

During the survey timeframe, Alliance members contributed to R&D on diverse AMR-relevant products or technologies. Overall, 33 surveyed companies reported a total of 314 diverse types of products in development, with AMR-relevant vaccines (n=96, 31%), antibiotics (n=82, 26%) and novel diagnostic platforms and assays (n=51, 16%) being the most common. Other products in development included 8 antifungals (3%), 18 repurposed/new applications of existing diagnostic platforms or assays (6%), 32 non-traditional and novel approaches[5] (10%), 7 software, hardware or middleware-related products (2%), 7 tools for AMR surveillance and/or epidemiology research (2%), and 13 other products[6] (4%). Over half of all products reported were attributed to the R&D pharma sector (n=181, 58%), followed by diagnostics (n=70, 22%), biotech/SMEs (n=47, 15%) and generics (n=16, 5%). See Annex A1 for further details.

Companies were also asked about the number of products they had in development. Data provided by companies on the number of products they had under development by phase was higher than the number of products they reported by type.[7] Nevertheless, the insights illustrate variety in the maturity of products in the pipeline.[8] More specifically, 33 companies reported on 374 products by development stage. **A quarter of these AMR-relevant products and/or technologies were in clinical trial phases I-III, but less than a tenth in later-stage phase III trials. Just under a quarter of products and/or technologies were in the early discovery phase** (n=86, 23%). More specifically, companies reported 86 products in early discovery phases (23%), 57 products in pre-clinical development (15%) and 94 products in clinical trials phases (25%) – of which 38 products were in phase I (10%), 27 in phase II (7%), and 29 in phase III trials (8%, mainly being R&D pharma products). Companies also reported 42 products in trial stages for diagnostic technologies (11%) and 61 in other[9] development phases (16%). Annex A1 provides further details.

How did Alliance members collaborate in R&D efforts and in sharing data?

AMR-relevant R&D is a collaborative endeavour. Between 1 April 2021 and 31 March 2023, all of the 34 R&D active Alliance members responding to the survey collaborated on R&D-related activities with other private sector organisations (85%, n=29), and over two-thirds (68% n=23) worked in partnerships with country-level government bodies and academic institutions. Over half (53%, n=18) also shared examples of partnerships with other types of organisations, such as not-for-profits, public-private partnerships and international AMR-focused initiatives or networks.

The majority of surveyed R&D active companies (82%, n=28 out of 34) **facilitated data sharing and/or exchange of information related to AMR-relevant R&D, and the types of data shared varied.** Among these companies, sharing data related to clinical trial results (44%, n=15) and epidemiology and/or surveillance (44%, n=15) were most commonly reported, followed by data on new compound leads relevant for AMR (41%, n=14), clinical trials design (38%, n=13) and new drug targets relevant for AMR (38%, n=13). Although many members engaged in data sharing and information exchange, there is scope to increase these activities in some key areas that could help facilitate an efficient R&D ecosystem. While commercial sensitivities would need to be considered, this includes, for example, clinical trial results and epidemiological and surveillance data.

What challenges to R&D investment did Alliance members experience, and what would influence decisions related to increasing investments in the future?

Despite a focused effort by many Alliance members to advance AMR-relevant R&D and innovation, companies experienced significant challenges during the survey timeframe. The most significant challenges affecting companies' decisions on whether and how much to invest in R&D for AMR-relevant products and/or technologies were market viability concerns, a lack of appropriate pull incentives/instruments and low historical sales volumes. More specifically, 82% of R&D active survey respondents 28 of 34 rated each of market viability concerns and a lack of appropriate package of pull incentives/instruments (e.g. advanced market commitments/guaranteed purchase funds, valuation mechanisms, reimbursement mechanisms) as challenging to a large or moderate extent, and 71% (n=24) felt this was also the case for historical sales volumes (i.e. low volumes). Other notable challenges that half or more of the responding companies considered as having an impact to a large or moderate extent were a lack of appropriate push incentives (e.g. external funding, tax credits) for the development of AMR-relevant products and/or technologies (62%, n=21), the high cost of the regulatory approval process (56%, n=19), and other priorities in the company (51%, n=14). There were a lot of similarities in key challenges experienced across sectors (see Annex A1 for more information).

It is also worth noting that 41% of R&D active companies responding to the survey (14 of 34) discontinued some AMR-relevant R&D programmes during the survey timeframe. While reasons for doing so varied, the three most common ones were high costs of R&D coupled with other priorities of the company (21%, n=7), scientific reasons (n=7, 21%) and poor market conditions, making a viable market unlikely (18%, n=6).

What will influence R&D investment decisions in the future and the impact of market conditions?

Close to three-quarters of R&D active surveyed companies would increase investments in R&D if market conditions improve (71%, n=24) and decrease investment if market conditions worsen (74%, n=25). In addition, over two-thirds of surveyed R&D active Alliance members indicated that they would maintain R&D investment levels even if the market conditions remain unchanged (68%, n=23), but over a quarter/close to a third (29%, n=10) stated that they would decrease investment. However, it is interesting to observe that half or more of surveyed R&D active generics and diagnostics companies (n=3 or 50% of generics and n=2 or 67% of diagnostics) would maintain investment levels event if market conditions worsen (though caution is advised with inferences from this observation given that the low absolute number of companies this represents is small and that the survey could not investigate the reasons for this).

Diverse factors shape market conditions, and companies responding to the survey also shared more nuanced insights on what influences investment decisions related to AMR-relevant R&D. **More than half of R&D active survey respondents rated five factors as likely to significantly influence company decisions on whether and/or how much to invest** (i.e. influencing these decisions either to a large or moderate extent). These are: (i) the existence of **stronger mechanisms that incentivise innovation, i.e. pull incentives** such as sufficiently sized subscription models, market entry award payments, transferrable patent exclusivity extensions, and guaranteed purchase funds/advanced market commitments (94%, n=32); (ii) **improving mechanisms that support access/availability,** including valuation models for novel products and/or technologies to capture full societal benefit and changes in reimbursement models to support patient access to novel antibiotics (88%, n=30); (iii) **greater streamlining and/or harmonisation of regulatory approval processes to make them more efficient** (79%, n=27); (iv) **improved push incentives** such as external funding and tax credits on R&D (65%, n=22) and (v) **waiving registration and evaluation fees for AMR-relevant products and/or technologies** (59%, n=20).

There were similarities and differences across sectors regarding which influences were seen as most significant, reflecting factors that matter most to them. For example, biotech and R&D pharma saw similar influences as critical (e.g. stronger mechanisms that incentivise innovation/pull incentives and improving mechanisms that support access/availability). Generics companies would also be motivated by stronger mechanisms that incentivise innovation/pull incentives and by greater streamlining, harmonising regulatory approval, waiving registration and evaluation fees, and improved push incentives (see Annex A1 for further details).

AMRIA contributions to tackling AMR through efforts to address access to antimicrobials and appropriate use

While R&D on novel antimicrobial products and related technologies is key to tackling AMR, it can take many years before products in development can reach patients in need, should they successfully complete clinical trials. The life sciences industry has an important role to play in supporting both patient access to and appropriate use of existing and novel AMR-relevant diagnostics, antimicrobials and vaccines.

Ensuring ***access to a sufficient supply of quality-assured*** diagnostics, antimicrobial treatments and vaccines is a key part of efforts to curb AMR (Anderson et al. 2019; Holmes et al. 2016). In this context, Alliance members are committed to removing barriers to equitable access to quality-assured antimicrobials globally and to efforts to reduce the prevalence of substandard and falsified AMR-relevant products. Related to these commitments is also a focus on collaborating with policymakers and other decision makers to foster conducive regulatory and economic environments for successful access efforts.

Antimicrobial stewardship and ensuring that existing antimicrobials are used appropriately to maintain their effectiveness are also key components of efforts to address the AMR challenge

(AMR Industry Alliance 2023). In the appropriate-use sphere, AMRIA commitments centre around promoting awareness and stewardship of antibiotic use. This includes commitments to slowing the emergence of resistance through a focus on prevention, vaccination and appropriate use, such as the collection and sharing of surveillance data with other stakeholders, to better understand resistance trends and monitor antimicrobial effectiveness. In addition, AMRIA efforts also seek to inform stakeholders about appropriate use, help develop infection control strategies and ensure that any promotional activities for antibiotics align with the goal of advancing stewardship (Anderson et al. 2023).

Box 2 below highlights key contributions of Alliance members to tackling AMR through efforts to improve access to quality-assured diagnostics, treatments and vaccines and to support appropriate use and access, with further details provided in the following narrative.

BOX 2. ACCESS AND APPROPRIATE USE: KEY INSIGHTS ON PROGRESS

Over two-thirds of Alliance members responding to the survey (67%) actively supported access to AMR-relevant products and/or technologies and did so in diverse ways: 72% of companies targeted the registration of AMR-relevant products and/or technologies with regulatory authorities, and 69% engaged in programmes to support affordability and ease of access. Two-thirds of companies (66%) engaged with access activities focused on securing product and technology availability, e.g. related to supply chain continuity and adapting products for new markets, and in advocacy efforts related to product approvals, quality, inclusion into clinical guidelines and appropriate use. Over half (52%) were active in **efforts focused on collaborative access mechanisms** (e.g. voluntary licensing agreements, sharing IP and distribution collaborations).

Nearly three-quarters of surveyed Alliance members (72%) implemented actions to support stewardship and the appropriate use of AMR-relevant products and/or technologies. The most common ways by which Alliance members contributed to appropriate use and stewardship during the survey timeframe were through education and awareness raising with diverse stakeholders (68% of companies with appropriate use activity), efforts to align antimicrobial product and/or technology promotion activities to AMR stewardship (61%), generating evidence and tools to support appropriate use and stewardship (58%) and collecting and/or sharing surveillance data (55%).

While the vast majority of companies in the R&D pharma, diagnostics and generics sectors actively contributed to access and appropriate use, there is some opportunity to scale up access activity by a minority of R&D pharma and generics Alliance members and appropriate-use-related activity by a minority of the generics sector. Biotechnology/SME companies were comparatively less active with access and appropriate use activity, which is not surprising given the stage of their products in development and business models in the sector.

How did Alliance members contribute to efforts to improve access to antimicrobials?

Over two-thirds of Alliance members responding to the survey (67%, n=29 out of 43) implemented activities related to supporting access to AMR-relevant products and/or technologies. This included all respondents in the diagnostics sector (100%, n=4), the majority of generics and R&D pharma sector respondents (80%, n=8 for generics and 75%, n=9 for R&D pharma) and just under half of biotech/SMEs (47%, n=8). The latter is not surprising as biotech companies often do not have products at stages ready for market entry, where access considerations become most prominent. However, going forward, there is some opportunity to focus on ensuring that all R&D pharma and generics companies with AMR-relevant products or technologies in the R&D pipeline or on the market contribute to access-related activities.

Access activities targeted diverse geographies/countries with different income levels: Out of the 29 companies that implemented access activities, two-thirds (66%, n=19) conducted activities to support access for each of high-income countries and low-income countries, and 72% (n=21) conducted activities to support access for each of upper middle-income countries and lower middle-income countries. There was some variety across sectors. For example, all but one (89%, n=8) R&D pharma respondents supported access for populations in each of lower middle-income and low-income countries. In comparison, three-quarters of diagnostics and generics respondents (75%, n=3 and n=6, respectively), undertook access activities in each of lower middle-income and low-income countries (see Annex A1 for further details).

The most common type of access-related activity was registering AMR-relevant products and/or technologies with regulatory authorities (72%; 21 of 29 respondents). Other common activities (i.e. taken by half or more of responding companies with access efforts) included **affordability-focused activities** (69%, n=20), e.g. through general pricing, tiered pricing, compassionate use programmes and product donations, and **activities related to ease of access** (69%, n=20), including working to ensure health systems capacity for appropriate access and use by those who need them, for example through appropriate distribution channels and support for health systems infrastructure. Two-thirds of respondents (66%, n=19) engaged with access activities **targeting availability** (e.g. supply chain continuity and stability for high-quality products/technologies and/or plans related to adapting existing products to new markets) and **advocacy** (e.g. for effective regulation for approval processes and ensuring quality products, for the inclusion of new diagnostics tools in healthcare guidelines, advocacy related to appropriate use of products and/or technologies). Over half (52%, n=15) also engaged in **partnerships/ collaborative access mechanisms** (e.g. voluntary licensing agreements where a patent holder allows others to manufacture, import, and/or distribute its patented product/technology, sharing IP with not-for-profits and collaborations around distribution, etc.). **Figure 2** provides further details overall and by sector.

FIGURE 2. DIVERSITY OF ACCESS-RELATED ACTIVITIES UNDERTAKEN BY ALLIANCE MEMBERS (N=29)

Source: RAND Europe analysis

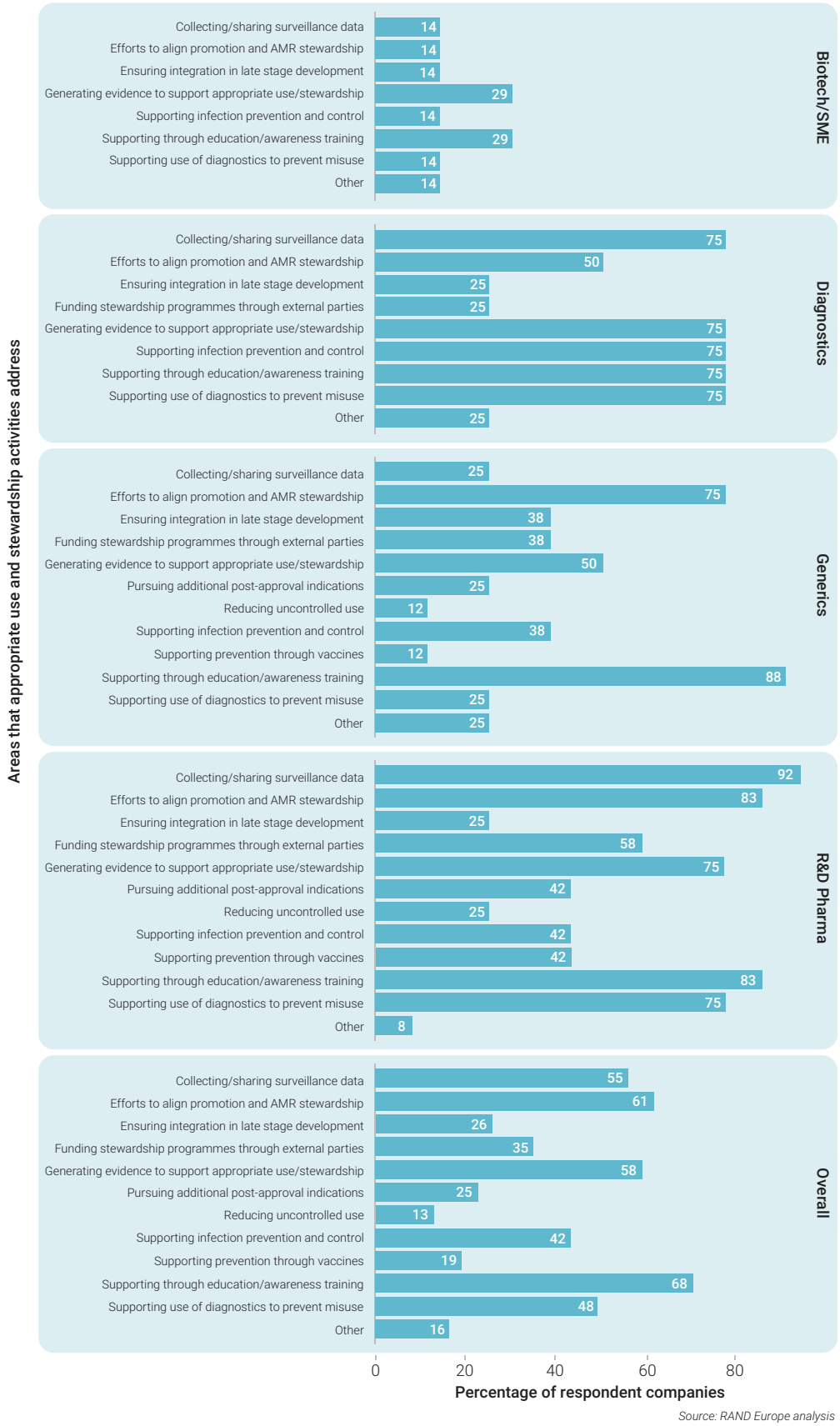
How have Alliance members helped tackle challenges related to antimicrobial stewardship and appropriate use?

Nearly three-quarters of Alliance members responding to the survey (72%; 31 of 43 companies) implemented activities related to appropriate use and stewardship for AMR-relevant products and/or technologies. This included all respondents from the R&D pharma and diagnostics sector (100%; n=12 and n=4, respectively) and the majority (80%, n=8) of generics sector companies. Fewer than half (41%, n=7) of biotech/SME respondents engaged with antimicrobial stewardship and appropriate use efforts, but this is to be expected given the business models that characterise the sector.

Companies engaged with diverse geographies on appropriate use and stewardship efforts, although just under half of those with appropriate use and stewardship activities pursued efforts targeting low-income countries. More specifically, 61% of the companies active with appropriate use and stewardship efforts (n=19) reported supporting such activities in high-income countries, 52% (n=16) for upper middle-income countries, 65% (n=20) for lower-middle-income countries and 45% (n=14) for low-income countries. While engagement patterns with low-income countries varied by sector (and although variation exists more generally among countries with different income levels), there is scope for enhancing engagement on appropriate use and antimicrobial stewardship targeted at the most resource-limited settings. See Annex A1 for further details.

The most common types of appropriate use and stewardship activities Alliance members implemented were related to education and awareness raising with diverse stakeholders (68% of companies with appropriate use activity engaged with this aspect, n=21); **efforts to align antimicrobial product and/or technology promotion activities to AMR stewardship** (61%, n=19); **generating evidence and tools to support appropriate use and stewardship** (58%, n=18) **and collecting and/or sharing surveillance data** 55%, n=17). Some additional efforts were also common for specific sectors (See Figure 3), such as companies supporting early, appropriate and/or expanded use of diagnostics to prevent antimicrobial misuse (e.g. this applied commonly to R&D pharma and diagnostics sector companies) and funding antimicrobial stewardship programmes (e.g. applies commonly to R&D pharma); supporting infection, prevention, and control (e.g. applies commonly to diagnostics). Biotechnology/SME companies were not highly active in the AMS space, which is not surprising given the stage of their products in development and business models.

FIGURE 3. DIVERSITY OF ANTIMICROBIAL STEWARDSHIP AND APPROPRIATE USE: RELATED ACTIVITIES BY ALLIANCE MEMBERS (N=31)



Source: RAND Europe analysis

In reflection on AMRIA member activities

Antimicrobial, vaccine and diagnostic innovation are key ingredients in global efforts to curb AMR, and Alliance members have made substantial contributions to R&D for novel AMR-relevant products and technologies during the survey timeframe. As this report shows, they have invested significant internal financial resources towards this end. In addition to using internal capabilities and infrastructure, Alliance members have worked in collaboration with others in the private, public and not-for-profit sectors to help pursue shared public health goals. Continuing to nurture and evolve collaboration could help leverage further synergies amongst Alliance members and the wider global landscape of actors committed to overcoming scientific and technological challenges to developing new vaccines, antimicrobials and diagnostic technologies.

Despite continued R&D efforts, the pipeline of products in late-stage development is limited, the future investment landscape is fragile and the need for sustainable incentives for industry-based innovation is a continual challenge. It is worth noting that some progress has been made by the global community in recent years, including most recently with efforts to introduce subscription-based payment models. But insights from this report, as well as recent wider

research on incentivising antimicrobial innovation, point to the urgency and need for a combination of diverse push and pull incentives to stimulate R&D sustainably and at scale to feed innovation pipelines for products and technologies that can effectively curb AMR and to help secure viable markets.

It is also important to keep sight of the value of information exchange and data sharing in efforts to use available resources efficiently and minimise unnecessary wastage or duplication of effort. While many Alliance members engaged with data sharing and information exchange, our analysis highlights an opportunity for a renewed focus on scaling activity for some types of data where commercial sensitivities allow (e.g. epidemiological and surveillance data but perhaps also clinical trial results).

R&D to develop novel antimicrobial products and technologies is part of the AMR challenge but must be understood as nested within wider related efforts to ensure access to and appropriate use of long-available and novel antimicrobials, AMR-relevant vaccines and diagnostic technologies. This is key in mitigating and managing further resistance threats. The majority of surveyed Alliance members actively supported efforts to secure access and appropriate use of antimicrobial products and technologies and did so in diverse ways. There is an opportunity to further mobilise some companies who may not currently be engaged in these aspects but have products nearing late-stage development or on the market in the future. Ensuring that appropriate use and access activities continue to target diverse geographies will help support AMRIA commitments going forward, including through potentially scaling up focus by companies on stewardship and appropriate use-related needs in the most resource limited settings.

AMRIA has been supporting its members by convening and coordinating activities for over five years to ensure focus on multiple areas of unmet need. We hope that the insights shared in this report will help support the Alliance as it evolves and inform how it continues to make its mark on addressing one of the biggest global public health concerns. We also hope that the findings will be informative for wider efforts to use evidence and insights in coordinating and mobilising the diverse landscape of industry policy-making bodies (e.g. governments, international authorities and agencies), regulatory bodies, not-for-profits, healthcare professionals and providers, civil society and the general public in responding to antimicrobial resistance as a collective challenge for society.

Endnotes

1 Membership numbers are based on membership at the time of the survey.

2 Range estimates are based on a combination of companies' data on the range of their investment values and absolute investment value figures for those companies investing US$20m or more, and where the companies did not see the absolute value of their investments as commercially sensitive information. Where companies responded by stating they invested US$20m or more but did not disclose an absolute value figure, we used US$20m in the calculations.

3 In the prior survey, 53 surveyed Alliance members (57% of all members at the time) reported investing US$1,804–1,952m in AMR-relevant R&D in total in FY 2019 and USD$1,798–1,936m in FY 2020. In the current survey, 34 Alliance member companies (44% of all Alliance members) invested an overall somewhat higher amount, as discussed in this report. While it is not possible to ascertain in the scope of this work, it is plausible that the overall relative increase in investment may be driven by some companies investing more at the individual level in absolute terms in comparison to the prior survey round.

4 More specifically, 47% reported a substantial increase of over 10% in value (n=16), and 38% stated that investment levels stayed approximately the same (n=13, 38%). A minority (15%, n=5) saw a comparative decline in investments.

5 Examples of what might fall into this category were provided in the survey design. Examples included live biotherapeutic products and/or technologies, monoclonal antibodies, microbiome modulators, biofilm dispersants, virulence inhibitors, immunomodulators, lysine and antibody-antibiotic conjugates.

6 Various types of examples were mentioned by some companies, such as those related to improving formulations or related to small molecules that inhibit biofilm, for example, though in principle, some of the 'other' products would also potentially fit as non-traditional products, such as small molecules to inhibit biofilm. Narrative information provided on examples of other products was often not elaborated on enough to ascertain the type of product and, in some cases, not detailed due to commercial sensitivities. In one case, commercial sensitivities meant that a company could provide numbers for some but not all of its products.

7 The reasons for this could not be explored within the scope of the survey.

8 While most companies reported consistent total numbers of products in response to questions on products

by development phase and type, this was not the case for 11 companies. The absolute value of the discrepancy ranged from 7–95% of the total number of products reported (using the larger of the two values). We dropped one outlier whose difference between the two reported numbers was 95% of the total number of products reported, with an absolute difference greater than 100; their data for the two questions are not reported here. For the remaining ten companies, the percentage discrepancy was 7–75%, with an absolute difference of 1–5 products.

9 Some examples companies provided included developing bioequivalence studies, improving formulations and Phase 4 or post-approval commitment studies. For further information and more examples, please see Annex A1.

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ABOUT THE AMR INDUSTRY ALLIANCE

The AMR Industry Alliance is a coalition of 77 biotechnology, diagnostic, generics, and research-based biopharmaceutical companies and 10 trade associations that was formed to drive and measure industry progress to curb antimicrobial resistance. The AMR Industry Alliance will ensure that signatories collectively deliver on the specific commitments made in the Industry Declaration on AMR and the Roadmap and will measure progress made in the fight against antimicrobial resistance.

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