amr INDUSTRY ALLIANCE
UNITED AGAINST ANTIMICROBIAL RESISTANCE

# ANNEX A1

## Technical annex

RAND EUROPE

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

RAND Europe is a not-for-profit policy research organisation that helps to improve policy and decision making through research and analysis. Our work benefits the public good.

# Section 1: R&D insights

## 1.1. Profile of survey respondents

A total of 43 out of 77 Alliance members completed the survey. The overall response rate was 56%.

The response rate varied by sector:

- R&D pharmaceutical: 100% (12 of 12)
- Generics: 100% (10 of 10)
- Diagnostics: 100% (4 of 4)
- Biotech/SMEs: 33% (17 of 51).

When interpreting the findings from the survey, some caution is advised, especially regarding the diagnostics sector, given the low number of companies in the Alliance from this sector.

It is also worth noting that approximately a third of all AMRIA biotech members responded to the survey; hence, their responses may not represent the Biotech Alliance members overall.

Of those who participated in the survey, the most common locations Alliance members reported having AMR-related activities in were Europe (77%, n=33), North and Central America (70%, n=30), and South East Asia (58%, n=25).

## 1.2. R&D investment

Overall, 34 of 43 respondents (79%) reported investing in R&D for AMR-relevant products and/or technologies in FY 2021 and FY 2022.

The percentage of companies who reported having invested varied by sector:

- R&D pharmaceutical: 92% (11 of 12). Note that one R&D pharmaceutical company did not invest in AMR-relevant R&D; the same company only had a minor level of investment in the prior survey reporting period.
- Generics: 60% (6 of 10); this result is unsurprising as the generics sector is by nature not focused on R&D as a core activity but does engage in some R&D, e.g. related to adapting formulations, new dosages or delivery methods and R&D on off-patent products.
- Diagnostics: 75% (3 of 4).
- Biotech/SMEs: 82% (14 of 17).

**For FY 2021, the range of total investments was US$1,959–2,035m, with the following ranges reported per sector:**

- Biotech/SMEs: US$110–154m
- Diagnostics: US$359–367m
- Generics: US$40–52m
- R&D pharmaceutical: US$1,450–1,462m.*

**For FY 2022, the range of total investments reported was US$1,971–2,047m, with the following ranges reported per sector:**

- Biotech/SMEs: US$94–138m
- Diagnostics: US$389–397m
- Generics: US$40–52m
- R&D pharmaceutical: US$1,448–1,460m.*

* We used US$20m in the calculations for three R&D pharmaceutical companies that did not provide specific investment amounts.

*Note: Investment levels are very similar to the previous survey round but attributed to a smaller number of companies (n=34), i.e. a smaller number of companies seem to have invested an equivalent amount to a larger number of surveyed companies in the previous round, where 53 surveyed Alliance members invested US$1,804–1,952m in FY 2019 and USD$1,798–1,936m in FY 2020. However, the profiles of respondent companies vary. Hence, direct comparisons need to be treated with caution and are not advised due to differing numbers of survey respondents and company profiles.*

In terms of how individual companies reported on their investment in R&D:

**There was substantial variety in spending levels across the Alliance, reflecting the diversity of alliance members regarding the types of companies and sectors represented in AMRIA.**

For FY 2021:

- Overall, 15% of companies (n=5) spent less than US$1m, 32% of companies (n=11) spent US$1–5m, 24% (n=8) spent US$6–20m, and 29% (n=10) spent over US$20m.
- As expected, R&D pharmaceutical companies had higher levels of investment at the sector level, with 64% (n=7) investing over US$20m in FY 2021.
- The majority of biotech/SMEs (57%, n=8) invested US$1–5m in FY 2021.
- Diagnostic and generics companies varied more widely in terms of their investment levels.

There were similar patterns of investment for FY 2022 as for FY 2021:

- Overall, 12% of companies (n=4) spent less than US$1m, 35% (n=12) spent US$1–5m, 21% (n=7) spent between US$6–20m, and 32% (n=11) spent over US$20m.

- At the sector level, 64% (n=7) of R&D pharmaceutical companies invested over US$20m in FY 2022.
- Over half (57%, n=8) of biotechs invested US$1–5m.
- Diagnostic and generics companies varied more widely in terms of their investment levels.

**Compared to FY 2020** (covered in the prior AMRIA reporting survey), **most companies (n=29, 85%) reported that investments either increased substantially or stayed approximately the same in FY 2021**:

- Nearly half of the 34 companies that invested in FY 2021 reported investments had increased substantially (over 10%) compared to FY 2020 (47%, n=16), and nearly 40% reported investments stayed approximately the same (38%, n=13).
- Overall, 15% of responding companies saw a comparative decline in investments: four companies reported that investments decreased somewhat (between 5% and 10%), and one reported that investments decreased substantially (more than 10%). This includes one biotech, two diagnostics and two R&D pharmaceutical companies.

**Of the responding companies that invested in R&D in FY 2021 and FY 2022, over two-thirds would maintain investment levels even if the market conditions remain unchanged. Nearly a third (29%) would decrease investment:**

- Some 68% (n=23) of the 34 companies that invested in R&D would maintain their investment level, 29% (n=10) would decrease investment, and 3% (n=1) would increase investment.
- By sector:
    - » Over half of companies within each sector would maintain current investment levels: 55% of R&D pharmaceuticals (n=6), 67% of diagnostics companies (n=2), 64% of biotechs/SMEs and diagnostics companies (n=9), and 100% of generics companies (n=6).
    - » However, 35% (n=5) of biotech/SMEs would decrease investment levels, 33% (n=1) of diagnostics companies would increase them, and 45% of R&D pharmaceutical companies (n=5) would also reduce investment. While the survey could not probe into the reasons, it is interesting to observe that 33% of diagnostics companies would increase investment. However, this is only a single company in absolute terms, given the low number of companies from the diagnostics sector in the Alliance.

**If market conditions improved, 71% (24 of 34) of companies with AMR-relevant R&D investments reported that they would increase their current level of investment, and 29% (n=10) reported that they would maintain their investment level.**

- There were similar patterns by sector, except for generics:
    - » In total, 92% (13 out of 14) of biotech/SMEs, 67% (2 of 3) of diagnostics companies, and 64% (7 of 11) of R&D pharmaceutical companies said they would increase investment. For generics companies, 67% (4 of 6) said they would maintain investment levels, and 33% (2 of 6) said they would increase investment.

**If market conditions worsen, nearly three-quarters of companies with AMR-relevant R&D investments (74%; 25 of 34) responded that they would decrease their current investment level:**

- By sector:
    - » The majority of biotech/SMEs and R&D pharmaceutical companies responded in a similar pattern, with 79% (n=11) and 91% (n=10) responding that they would decrease their current investment levels, respectively. Half of generics companies (50%, n=3) said they would maintain their investment level, with the other half indicating they would decrease their investment. For diagnostics companies, 67% (n=2) said that they would maintain their current investment levels, whereas 33% (n=1) said they would decrease them.
    - » Interestingly, half or more of generics or diagnostics companies would maintain investment levels even if market conditions worsen. However, the survey could not probe into the reasons for this.

## 1.3. Product phases of development

**Alliance members reported 374 AMR-relevant products and/or technologies in development during the survey reporting period.**

**As expected, there were comparatively fewer products of the total (n=374) in the later stages of development:**

- Early discovery: 23% (n=86)
- Pre-clinical: 15% (n=57)
- Clinical: Phase I clinical trials: 10% (n=38)
- Clinical: Phase II clinical trials: 7% (n=27)
- Clinical: Phase III clinical trials: 8% (n=29)
- Clinical: Clinical trials stages for diagnostics and technologies: 11% (n=42).

**Over a third (36%) of alliance member AMR-relevant products and/or technologies were in clinical trial phases (136 of the reported 374 products in development). However, less than a tenth (8%, n-29) were reported to be in the later stage phase III trials** (and these were mainly R&D pharmaceutical products).

Just under a quarter (23%) of the reported 374 AMR-relevant products and/or technologies were in the early discovery phase (n=86).

However, there were differences by sector:

- Of all R&D pharmaceutical products, 43% (n=80) were in clinical trial phases – 30 products in Phase 1, 22 in Phase 2 and 28 in Phase 3. However, it is important to note that 15% of R&D pharmaceutical products (n=28) were in (late) Phase 3 trials. Nearly a third of R&D pharmaceutical products were in early discovery phases (30%; 55 of 186). *Note: One R&D pharmaceutical company could not disclose the number of their products in development. They explained that their AMR-relevant products span early discovery, pre-clinical, and phase I trials.*
- One biotech/SME product was also in Phase 3 trials. For biotech/SMEs, 41% of products were in early discovery (26 out of 64) and 33% were in pre-clinical trials (n=21).
- Over half of the products reported by diagnostics companies (53%; n=37) were in clinical trial stages. For diagnostics, 47% (n=33) reported other phases of development. The narrative on this was not always clear, and some respondents used it to briefly elaborate on specific options, including: funding an in-house early discovery program that has advanced from lead identification to a candidate (although this is how the company in question reported it, it could also be seen as constituting early discovery); general comments on developing antimicrobial resistance drugs or specific compounds, progressing a clinical candidate into first-in-human studies in healthy volunteers and developing back-up series belonging to Novel Bacterial Topoisomerase Inhibitors (NBTI); products in phase 1 trials, developing bioequivalence studies; improving formulations, assets in technical lifecycle development; phase 4 studies or a post-approval commitment study; post registrative trials, projects in registration phase or life cycle management phases, emergency use authorisation and post-marketing studies.
- For generics companies, a smaller percentage of products were in early discovery phases (n=5, 25% respectively) or pre-clinical phases (n=8, 40%)

## TABLE 1. REPORTED AMR-RELEVANT PRODUCTS BY PHASE OF DEVELOPMENT.

| Sector | Early discovery | Preclinical | Clinical: Phase I clinical trials | Clinical: Phase II clinical trials | Clinical: Phase III clinical trials | Clinical: Clinical trial stages for diagnostics and technologies | Other | Total products and/or technologies invested in | Number of companies responded (n) |
|---|---|---|---|---|---|---|---|---|---|
| Biotech | 26 | 21 | 8 | 5 | 1 | 0 | 3 | 64 | 13 |
| Diagnostics | 0 | 0 | 0 | 0 | 0 | 37 | 33 | 70 | 3 |
| Generics | 5 | 8 | 0 | 0 | 0 | 0 | 7 | 20 | 6 |
| R&D | 55 | 28 | 30 | 22 | 28 | 5 | 18 | 186 | 11 |
| Total | 86 | 57 | 38 | 27 | 29 | 42 | 61 | 374 | 33 |

*Note: there is a difference in the number of products reported by development phase and product type. This is driven by inconsistencies in the data reported by a few companies. It is beyond this project's scope to conduct a data audit, but for informational purposes, 379 products were reported on in the question about development phases; 458 products were reported on in the question about product types, leading to a difference of 79 products. The data is driven by reporting differences between the two questions for 11 companies, with one company being an outlier in the scale of the difference. This outlier was excluded from the analysis of these two questions (products by phase of development and by product type).*

## TABLE 2. REPORTED AMR-RELEVANT PRODUCTS BY PRODUCT TYPE.

| Sector | Antibiotics | Antifungals | AMR-relevant vaccines | Non-traditional and novel approaches | New diagnostic platforms or assays | Repurposed/ new application of existing diagnostic platforms or assays | Software, hardware, or middleware | Tools for AMR surveillance and/or epidemiology research | Other | Total products and/or technologies invested in | Number of companies responded (n) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Biotech | 13 | 0 | 1 | 20 | 0 | 0 | 0 | 0 | 13 | 47 | 13 |
| Diagnostics | 0 | 0 | 0 | 0 | 45 | 17 | 3 | 5 | 0 | 70 | 3 |
| Generics | 13 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 16 | 6 |
| R&D | 56 | 7 | 95 | 11 | 6 | 1 | 4 | 1 | 0 | 181 | 11 |
| Total | 82 | 8 | 96 | 32 | 51 | 18 | 7 | 7 | 13 | 314 | 33 |

*Note: One outlier excluded from this analysis.*

**The most common types of products in development were antibiotics. However, Alliance members also engaged in developing AMR-relevant vaccines, diagnostic platforms or assays and other types of AMR-relevant products and technologies.**

Out of a total of 314 products reported for this question, the proportions of each type reported were as follows:

- Antibiotics: 26% (n=82)
- AMR-relevant vaccines: 31% (n=96)
- New diagnostic platforms or assays: 16% (n=51)
- Other types of products in development: 27% (n=85), including:
    - » Non-traditional and novel approaches: 10% (n=32)
    - » Antifungals: 3% (n=8)
    - » Repurposed/new applications of an existing diagnostic platform: 6% (n=18)
    - » Software, hardware or middleware: 2% (n=7)
    - » Tools for AMR surveillance and/or epidemiology research: 2% (n=7)
    - » Not elaborated on: 4% (n=13).

By sector:

- R&D pharmaceutical companies drove most antibiotic development efforts (56 of 82 reported products).
- R&D pharmaceutical companies drove most AMR-relevant vaccine development (95 of 96 products in development).
- Diagnostics companies drove the majority of new diagnostic platforms or assays (45 of 51 products), repurposed or new applications of existing diagnostic platforms and assays (17 of 18 products), and tools for AMR surveillance (5 of 7 products).

## 1.4. Partnerships

**The most common partnerships were AMRIA-member company partnerships with other private sector organisations. However, over half of the responding companies also reported partnerships with country-level government bodies and academic institutions.** More specifically:

- A total of 85% of companies (29 of 34 respondents for this question) reported partnerships with other private sector or industry organisations, 68% of companies (n=23) reported partnerships with country-level government bodies, and 68% of companies (n=23) reported partnerships with academic institutions.
- Some 18 out of 34 (53%) companies reported other partnerships. Examples spanned partnerships with not-for-profits and non-governmental organisations, such as the National Institutes of Health (NIH), National Science Foundation (NSF), Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), U.S. Army Medical Research Institute of Infectious Diseases (AMRIID), Global Antibiotic Research and Development Partnership (GARDP), Centre for Cellular And Molecular Platforms (C-CAMP), India AMR Innovation Hub (IAIH), Wellcome Trust, United States Department of Defense, European Commission, TB Alliance, Stop TB, Global Drug Facility (GDF), KNCV Foundation, the European Investment Bank and various public-private partnerships and collaborations with contract research or contract manufacturing organisations.

## 1.5. Challenges to R&D investment

Among the 34 companies that responded to the question on challenges to investment in AMR-relevant R&D, **the three most frequently selected challenges to companies' investment levels/ decisions 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:

- A total of 68% (n=23) of respondents saw market viability concerns related to a lack of clear and stable market size and/or uncertain prescriber and/or payer behaviour' as a significant challenge (i.e. rated it as a challenge 'to a large extent').
- Some 62% (n=21) saw the lack of an appropriate package of pull incentives/instruments in general (either in scale or nature of incentives as a significant challenge (i.e. rated the factor as challenging 'to a large extent').
- Overall, 56% (n=19) saw historical sales volumes (e.g. low volumes) as a significant challenge (rated the factor as challenging 'to a large extent').

Other challenges (21%, n=7): Lack of equity capital, lack of outside venture capital availability, no interest from the public market in companies developing products for AMR, no M&A for AMR product companies, regulatory capabilities and changes in country regulatory processes and a lack of perception of AMR importance.

**There is considerable similarity in what were considered the key challenges across sectors. By sector, the following challenges were considered particularly significant** (note: we first

highlight those where half or more of a sector's respondents identified something as a challenge 'to a large exten't; we then note challenges identified as impacting 'to a large extent' by a third or more of sector respondents):

- For R&D pharmaceutical companies:
    - » Market viability concerns (n=9, 82%), a lack of appropriate package of pull incentives/instruments in general (n=7, 64%), and historical sales volumes (n=6, 55%) were seen as a key challenge by half or more of the sector respondents.
    - » Other priorities in the company were also considered a challenge by over a third of R&D pharmaceutical respondents (n=4, 36%).
- For generics companies:
    - » Half or more generics companies noted market viability concerns (n=4, 67%), historical sales volumes (n=4, 67%), a lack of appropriate package of pull incentives/instruments in general (n=3, 50%) and the high costs of the regulatory approval process (n=3, 50%) as key challenges.
    - » Other priorities in the company were also seen as challenging by a third of generics respondents (n=2, 33%).
- For biotech companies:
    - » A lack of appropriate package of pull incentives/instruments in general (n=11, 79%), market viability concerns (n=8, 57%) and historical sales volumes (n=8, 57%) were seen as a significant challenge (i.e. challenging 'to a large extent') by over half of biotech survey respondents.
    - » The high cost of the regulatory approval process is also worth noting, seen as a challenge 'to a large extent' by over a third of biotech survey respondents (n=5, 36%).
- For diagnostics companies:
    - » Over two-thirds of diagnostics companies saw market viability concerns (n=2, 67%) as a key challenge.
    - » Other challenges considered to have had an impact 'to a large extent' by at least a third of diagnostics companies were historical sales volumes (n=1, 33%) and other company priorities (n=1, 33%).

**Significant challenges were seen as having an impact either to a 'large' or 'moderate' extent** by half or more of respondents. A large percentage of respondents rated each of the options below as challenging **to a 'large' or 'moderate' extent**:

- A total of 82% (n=28) rated a lack of an appropriate package of pull incentives/instruments in general, either in scale or in the nature of the incentives, as challenging to a large or moderate extent.
- Some 82% (n=28) rated market viability concerns as challenging to a large or moderate extent.

- Some 71% (n=24) rated historical sales volumes as challenging to a large or moderate extent (e.g. low volumes as a challenge), influencing investments going forward.
- A total of 62% (n=21) rated a lack of appropriate push incentives for the development of AMR-relevant products and/or technologies as challenging to a large or moderate extent.
- Some 56% (n=19) rated the high cost of the regulatory approval process as challenging to a 'large' or 'moderate' extent.
- Overall, 51% (n=14) rated other priorities in the company as challenging to a 'large' or 'moderate' extent.
- A total of 35% (n=12) rated the risk of R&D/scientific failure for AMR products/technologies as challenging to a large or moderate extent.

## 1.6. Influences on investment

Regarding influences on potentially increasing investment levels, **half or more of the 34 companies responding to this question saw stronger mechanisms that incentivise innovation and improved mechanisms to support access/availability as particularly important potential levers** (i.e. rated them as likely to influence 'to a large extent'). More specifically:

- Some 76% (n=26) of companies felt that this applies to (i) 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.
- Some 56% of respondents (n=19) felt this applies to (i) 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.

Other influences (24%, n=8) include global incentives that support long-term sustainability, accelerated approval in emerging countries, acceptance that both biofilm and One Health are key issues to control AMR, greater commitment from large commercial pharmaceutical companies, using a variety of pull incentives to fix the AMR business model, outside venture capital availability.

**Regarding sector-specific observations, there were similarities and differences across sectors, reflecting factors that matter most to them.** For example, biotech/SMEs and R&D pharmaceutical companies saw similar influences as influential to a large extent (e.g. stronger mechanisms that incentivise innovation/pull incentives and improving mechanisms that support access/availability, whereas generics companies would also be incentivised by stronger mechanisms that motivate innovation/pull incentives to a large extent but also by streamlining and/or harmonising regulatory approval, waiving registration and evaluation fees, and improving push incentives. (Note regarding sector-specific bullets that follow: we first highlight those where half or more of a sector's respondents identified something as a challenge 'to a large extent; we then note influences identified as impacting 'to a large extent' by a third or more of sector respondents):

- For R&D pharmaceutical:
    - » Some 91% (n=10) selected stronger mechanisms that incentivise innovation, i.e. pull incentives as an influence to a large extent. A total of 64% (n=7) rated improving mechanisms that support access/availability as an influence to a large extent.
- For biotechs/SMEs (and similar to R&D pharmaceutical):
    - » Some 86% (n=12) selected stronger mechanisms that incentivize innovation as an influence to a large extent, and 64% (n=9) rated improving mechanisms that support access/availability as an influence to a large extent.
    - » Other factors seen as influencing 'to a large extent' by at least a third of biotech/SME companies was improved push incentives (e.g. grant funding, tax credits for AMR R&D) (n=5, 36%).
- For generics:
    - » Some 67% (n=4) saw greater streamlining and/or harmonisation of regulatory approval as a force that would influence them to a large extent, 50% (n=3) rated each of stronger mechanisms that incentivise innovation, waiving registration and evaluation fees, and improved push incentives as an influence to a large extent.
    - » Other factors seen as influencing to a large extent by at least a third of generics companies were improving mechanisms that support access/availability (33%, n=2).
- For diagnostics:
    - » There were no options that 50% or more of diagnostics companies (given n=3) rated as influencing 'to a large extent' the likelihood of investment into R&D. However, factors seen as influencing 'to a large extent' by at least a third of diagnostics companies were improving mechanisms that support access/availability (n=1, 33%), stronger mechanisms that incentivise innovation (n=1, 33%), and greater streamlining and/or harmonisation of regulatory approval processes (n=1, 33%).

**Significant influences that were considered as having an impact to either 'a large' or 'moderate' extent** by half or more of respondents: Five instruments/incentives/conditions were rated as influencing either **to a large or 'moderate extent**:

- Some 94% (n=32) rated stronger mechanisms that incentivise innovation, i.e. pull incentives, as influencing to a large or moderate extent.
- A total of 88% (n=30) rated improving mechanisms that support access/availability as influencing to a large or moderate extent.
- Some 79% (n=27) rated greater streamlining and/or harmonisation of regulatory approval processes to make them more efficient as influencing to a large or moderate extent.

- Some 65% (n=22) rated improved push incentives as influencing to a large or moderate extent.
- Some 59% (n=20) rated waiving registration and evaluation fees for AMR-relevant products and/or technologies as influencing to a large or moderate extent.

## 1.7. Programme discontinuation

**Fewer than half of respondent companies discontinued AMR-relevant R&D programmes** (41%; 14 of 34).

Reasons for discontinuing AMR-relevant R&D programmes varied, but the three most common ones were(though still selected from a menu of options by approximately a fifth of respondents):

- » Some 21% (n=7) out of the 34 respondents discontinued R&D programmes for reasons related to the high costs of R&D coupled with other company priorities.
- » Some 21% (n=7) cited 'scientific reasons'.
- » Some 18% (n=6) selected 'poor market conditions making likelihood of viable market unlikely'.

Examples of other reasons for discontinuation included commercially sensitive reasons and technology challenges driving R&D costs too high in combination with the market/ reimbursement conditions, and other strategic business decisions, high costs of R&D and other competing priorities (n=2).

## 1.8. Data sharing

**The majority of responding companies - 82%** (28 of 34) **facilitated data sharing and/or exchange of information related to R&D for AMR-relevant products and/or technologies.**

A third or more of the responding companies shared:

- Data related to clinical trial results (44%, n=15)
- Data on epidemiology and/or surveillance (44%, n=15)
- Data related to new compound leads relevant to AMR (41%, n=14)
- Data related to clinical trial design (38%, n=13)
- Data related to new drug targets relevant to AMR (38%, n=13)
- Other examples provided include information on the status of a project in a company, data related to antibiotics used with the G-PPS (Global Point Prevalence Survey) initiative, data related to test development in a peer-reviewed publication and at conferences, progress with platform development, assay coverage data and performance on clinical samples and data related to new drug targets relevant to AMR.

# Section 2: Access efforts

## 2.1. Access activities' presence and location

**Over two-thirds (67%; 29 of 43) of survey respondents implemented activities related to supporting access to AMR-relevant products and/or technologies.** By sector:

- Diagnostics: 100% (n=4) [caution in interpretation advised due to the small absolute number]
- Generics: 80% (n=8)
- R&D pharmaceutical: 75% (n=9)
- Biotech/SMEs: 47% (n=8).

**Biotech companies often do not have products ready for market entry, so the lower percentage is unsurprising.**

**It is somewhat more surprising that not all R&D pharmaceutical and generics companies were involved with access activities.**

**Access activities targeted diverse** geographies/countries with different income levels. Of the 29 companies that implemented access activities:

- Some 66% of respondents (n=19) reported undertaking activities to support access for high-income countries.
- A total of 72% (n=21) reported undertaking activities to support access for upper middle-income countries.
- Some 72% (n=21) reported undertaking activities to support access for lower middle-income countries.
- A total of 66% (n=19) reported undertaking activities to support access for low-income countries.

By sector:

- For R&D pharmaceutical:
    - » Of R&D pharmaceutical companies who engaged with access activities, 100% (n=9) undertook activities to support access for (i) high-income countries and (ii) upper middle-income countries; 89% (n=8) of R&D pharmaceutical companies undertook activities to support access for (iii) lower middle-income countries and (iv) low-income countries.

- For diagnostics:
    - Some 50% (n=2) undertook activities in high-income countries; 100% (n=4) of diagnostics undertook activities in upper middle-income countries; 75% (n=3) undertook activities in each of lower middle-income and low-income countries.
- For generics:
    - Overall, 63% (n=5) of generics undertook activities in both high-income and upper middle-income countries, respectively; 88% (n=7) and 75% (n=6) of generics undertook activities in both lower middle- and low-income countries, respectively, and 13% (n=1) selected the 'none of the above' option, indicating that their activities were not specific to the countries' income level (further detail is unavailable).
- For biotech/SMEs:
    - Some 38% (n=3) of biotechs undertook activities in high, upper middle-, and upper lower-income countries, respectively; 25% (n=2) undertook activities in low-income countries, and 50% (n=4) selected the 'none of the above' option, indicating that their activities were not specific to countries' income level (further detail is unavailable).

## 2.2. Types of access activities

- The most common type of access-related activity reported by survey respondents was **registration of products and/or technologies with regulatory authorities** (72%; 21 of 29 respondents). Other common activities reported by half or more of the respondents were:
    - Affordability activities: 69% (n=20) engaged in affordability activities through general pricing, tiered pricing, compassionate use programmes, product donations, etc.
    - Activities related to ease of access: 69% (n=20) engaged in activities related to ease of access, such as working to ensure health systems capacity for appropriate access and use by those who need them, e.g. through appropriate distribution channels and support for health systems infrastructure.
    - Availability activities: 66% (n=19) engaged in availability activities, such as supply chain continuity and stability for high-quality products/technologies and/or plans related to adapting existing products to new markets.
    - Advocacy activities: 66% (n=19) engaged in advocacy activities, such as advocacy for effective regulation for approval processes and ensuring quality products, advocacy for including new diagnostics tools in healthcare guidelines, advocacy related to the appropriate use of products and/or technologies, etc.
    - Partnerships/collaborative access mechanisms: 52% (n=15) engaged in **partnerships/collaborative access mechanisms, such as** 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.

- By sector (where 50% or more of respondents reported engaging in an activity):
    - » R&D pharmaceutical companies primarily engaged in a diverse set of access-related activities. More than half of R&D pharmaceutical companies report engaging in regulatory registration (100%, n=9), availability (100%, n=9), affordability (100%, n=9), ease of access (89%, n=8), partnerships/collaborative access mechanisms (89%, n=8), advocacy (n=8, 89%) and reducing the prevalence of substandard and/or falsified products/technologies (78%, n=7).
    - » Biotechs do not have a high engagement level in access activities. This is unsurprising given the product development stages for many biotechs. The most common are activities focused on improving ease of access (50%, n=4).
    - » Diagnostics engage primarily in regulatory registration (75%, n=3), affordability (75%, n=3), ease of access (75%, n=3), advocacy (75%, n=3), availability (50%, n=2), and partnerships/collaborative access mechanisms (50%, n=2).
    - » Generics engage in access activities related to regulatory registration (100%, n=8), availability (88%, n=7), affordability (75%, n=6), reduced prevalence of substandard and/or falsified products/technologies (75%, n=6), advocacy (62%, n=5) and ease of access (n=5, 62%).
- Other types of access activities were reported under 'other', including supporting antimicrobial stewardship and physician training on the appropriate use of antibiotics and contributing to the AMR Action fund.

## 2.3. DEI and access

Diversity, Equality and Inclusion (DEI) considerations were explicit in 66% (19 out of 29) of companies' access-related plans or strategies. Some 28% (n=8) did not know the status of DEI considerations in their access-related plans or strategies.

# Section 3: Appropriate use and stewardship

## 3.1. Appropriate use and stewardship activities: Presence and location

**Overall, 72% of companies (31 of 43) implemented activities related to the appropriate use and stewardship of AMR-relevant products and/or technologies.**

**By sector, the proportion of companies that implemented such activities was fairly high** (ranging from 80–100% except for biotech/SMEs (41%), which may be related to the variety in biotech business models and development stages but could not be explored within the scope of this work). The proportion who implemented appropriate use and stewardship activities was as follows:

- R&D pharmaceutical companies: 100% (n=12)
- Diagnostics companies: 100% (n=4)
- Generics companies: 80% (n=8)
- Biotechs/SMEs: 41% (n=7).

Companies engaged with diverse geographies on appropriate use and stewardship efforts, although just under half did so with low-income countries:

- Some 61% of respondents (19 out of 31 with appropriate use and stewardship activities) reported undertaking activities to support appropriate use and stewardship for high-income countries.
- Some 52% (n=16) reported undertaking activities to support appropriate use and stewardship for upper middle-income countries.
- Some 65% (n=20) reported undertaking activities to support appropriate use and stewardship for lower middle-income countries.
- Some 45% (n=14) reported undertaking activities to support appropriate use and stewardship for low-income countries.

**Apart from R&D pharmaceutical and diagnostics companies, activity related to low-income countries was relatively low, which may be surprising for the generics sector.**

By sector:

- R&D pharmaceutical: 83% (n=10) in high-income, 67% (n=8) in upper middle-income, 75% (n=9) in lower middle-income, and 58% (n=7) in low-income countries; 8% (n=1) reported none of the above or that the activities were not specific to the countries' income level.

- Biotechs: 43% (n=3) undertook activities in high-income countries, 29% (n=2) in upper middle-income countries, 43% (n=3) in lower middle-income countries and 14% (n=1) in low-income countries; 43% (n=3) reported none of the above or that the activities were not specific to the countries' income level.
- Diagnostics: 100% (n=4) in high-income countries, 50% (n=2) in upper middle-income countries, and 75% (n=3) each in lower middle-income and low-income countries, respectively.
- Generics: 25% (n=2) in high-income countries, 50% (n=4) in upper middle-income countries, 63% (n=5) in lower middle-income countries, and 38% (n=3) in low-income countries; 38% (n=3) selected none of the above, i.e. the activities are not specific to the countries' income level.

## 3.2. Appropriate use and stewardship activities

The most common areas of appropriate use and stewardship activities that survey respondents engaged in (where 50% or more of respondents reported engaging in an activity) were as follows:

- Education and awareness-raising activities: 68% (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).
- Collecting and/or sharing surveillance data: 55% (n=17).

By sector:

- R&D pharmaceutical: 92% (n=11) collected/shared surveillance data; 83% (n=10) participated in education and awareness-raising activities; 83% (n=10) underwent efforts to align antimicrobial product and/or technology promotion activities to AMR stewardship; 75% (n=9) selected supporting early, appropriate and/or expanded use of diagnostics to prevent antimicrobial misuse; 75% (n=9) generated supporting evidence and tools, and 58% (n=7) funded antimicrobial stewardship programmes.
- Diagnostics: 75% (n=3) reported activities supporting infection, prevention, and control (IPC); supporting early, appropriate and/or expanded use of diagnostics to prevent antimicrobial misuse; generating supporting evidence and tools; collecting/sharing surveillance data; education and awareness raising activities. Some 50% (n=2) underwent efforts to align antimicrobial product and/or technology promotion activities with AMR stewardship.
- Generics: 88% (n=7) participated in education and awareness-raising activities; 75 % (n=6) underwent efforts to align antimicrobial product and/or technology promotion activities to AMR stewardship; 50% (n=4) generated supporting evidence and tools.

- Biotechnology/SME companies: These were not highly active in the AMR space, which is unsurprising given the stage of their products in development and business models. Most common (but still only undertaken by less than a third of respondents) were activities supporting infection, prevention, and control, and 29% (n=2) generating supportive evidence and tools (29%, n=2).
- Additional examples were provided under other activity types. These included working with policies on pull incentives, funding AMR education programmes and partnerships with groups/agencies involved in AMR like the Center for Infectious Disease Research and Policy (CIDRAP), discussions around pricing to give access to quality and affordable products, AMR campaigns and engaging with digital decision support for AMR.

## 3.3. DEI

DEI considerations were explicit in 48% (n=15) of respondent companies' appropriate use and stewardship-related plans or strategies. Overall, 39% (n=12) did not know the status of their DEI considerations in appropriate use and stewardship strategies or plans.

# Section 4: Manufacturing and the environment

## 4.1. Owned manufacturing sites overview

**Overall, 95% of all survey respondents (21 of 22 companies in the R&D pharmaceutical and generics sectors) owned manufacturing sites**. This included ten generics companies and eleven R&D pharmaceutical companies. The one company that reported not having its own manufacturing sites belonged to the R&D pharmaceutical sector.

**The remaining 21 companies reported 199 owned antibiotic manufacturing sites in total. Of these:**

- Sixty-seven per cent (n=134) were from generics companies, and 33% (n=65) were from R&D pharmaceutical companies.
- Generic respondents reported a mean of 13 manufacturing sites (range = 3–33).
- R&D pharmaceutical respondents reported a mean of five owned antibiotic manufacturing sites (range = 1–21).

## 4.2. Owned manufacturing sites and CAMF assessment

**Overall, 95% of owned manufacturing sites (189 of the 199 sites) had been assessed against the CAMF criteria in the last five years.**

By sector:

- Generics: 95% of owned manufacturing sites had been assessed against CAMF (127 of 134).
- R&D pharmaceutical: 95% of sites had been assessed against CAMF (62 of 65).

In total, 86% (18 of the 21) of companies with owned manufacturing sites had all of their sites assessed against CAMF criteria:

- A total of 18 companies (86%) had assessed all of their sites against CAMF: eight out of ten generics with their owned manufacturing sites (80%) and 10 out of 11 R&D pharmaceutical companies with their owned manufacturing sites (91%).
- Two companies assessed some but not all of their owned manufacturing sites (both generics companies, i.e. 20% of generics companies with owned manufacturing sites).
- One company assessed none of their sites (one R&D pharmaceutical company, 9% of all R&D pharmaceuticals with owned manufacturing sites).

**A total of 20 of 21 companies (95%) assessed one or more of their sites against CAMF criteria.** One company reported that none of their owned manufacturing sites were assessed; hence, they could not know whether their sites meet CAMF requirements.

- Some 50% of all companies assessing one or more of their sites against CAMF criteria (10 out of 20) reported that all (100%) of their owned manufacturing sites fully met the CAMF requirements; this included four generics and six R&D pharmaceutical companies.
- For the remaining eight companies, the percentage of owned manufacturing sites fully meeting CAMF requirements fully varied widely, from between 13–93% of owned manufacturing sites fully meeting CAMF requirements:
    - » R&D pharmaceutical: 90% (9 of 10) of companies with at least some sites fully meeting CAMF criteria reported that half or more of their sites fully met CAMF requirements.
    - » Generics: 80% of companies (4 of 5) with at least some sites fully meeting CAMF criteria reported over half of their sites fully met CAMF requirements.
- For another two companies (10% of companies with at least some of their owned manufacturing sites assessed against CAMF criteria, i.e. one generics and one R&D pharmaceutical company), none fully met CAMF requirements.

Overall, 40% of companies assessing one or more own sites against CAMF criteria (8 of 20) reported having sites that partially met the CAMF requirements, with the number of sites partially meeting CAMF ranging widely from 7–89%:

- Generics: 40% (two of five companies with one or more sites assessed against CAMF) reported that at least half of their sites partially met CAMF requirements.
- R&D pharmaceutical: 33% (one of three companies with one or more sites assessed against CAMF) reported that at least half of their sites partially met CAMF requirements.

**Some 15% (3 of 20) of companies assessing one or more own sites against CAMF reported having some sites that did not meet CAMF requirements, with the number of sites not meeting requirements ranging from 11–36%** (i.e. no companies where over half of their sites did not meet CAMF requirements).

Of the twenty companies that assessed their owned sites against CAMF, **the most common actions taken to ensure that owned manufacturing sites met CAMF** (i.e. actions taken by more than half of the companies) **were:**

- Operating procedures: 75% (n=15).
- Training provision to support improvement practices in owned sites to meet framework expectations: 75% (n=15).
- Improvement plans: 65% (n=13).

Notably, more than a third of companies also added wastewater treatment capacity or different wastewater treatment technology (40%; 8 of 20 companies).

Additional actions were taken, and narrative examples were shared, including gap analysis, establishment of Mass Balance template, development of a test method to detect antibiotics in wastewater, confirming compliance through audits and engaging with BSI certification against the standard.

## 4.3. Products manufactured at own manufacturing sites and PNEC targets

**The 21 respondents who owned manufacturing sites manufactured a total of 800 antibiotic products there.** Of these, 66% of the products (n=529) were from generics companies and 34% (n=271) from R&D pharmaceutical companies:

- Generics companies reported a mean of 53 products (range = 12–114); R&D pharmaceutical companies reported a mean of 25 products (range = 1–118 per company).

Overall, 88% of all products manufactured at owned manufacturing sites were assessed against PNEC targets at owned sites, equating to 700 products assessed against PNEC targets:

- Generics companies had an 86% assessment rate (453 of 529 products were assessed), i.e. 86% of all generics company products manufactured at owned sites were assessed against PNEC targets.
- R&D pharmaceutical companies had a 91% assessment rate (247 of 271), i.e. 91% of all R&D pharmaceutical company products manufactured at owned sites were assessed against PNEC targets.

A total of 76% (16 of 21) of companies with owned sites assessed all their products against PNEC targets:

- Overall, 70% (7 of 10) generics companies with products manufactured at owned sites and 82% (n=9) of 11 R&D pharmaceutical companies with products manufactured at owned sites.

**Some 14% (3 out of 21) companies with owned sites assessed some of their products against PNEC targets:**

- These comprised 30% (3 of 10) generics companies with products manufactured at owned sites. For these three companies, the per cent of products assessed ranged from 46–82%.

**A total of 10% (2 out of 21) companies with owned sites did not assess any of their products** against PNEC targets:

- These comprised 18% (2 of 11) of R&D pharmaceutical companies with products manufactured at owned sites.

Overall, 84% of products from owned manufacturing sites (487 out of 582) assessed against PNEC targets and for which assessment results could be provided met PNEC criteria:

- One company could not provide data on how many of their assessed products met PNEC targets. Thus, for assessed products that met PNEC targets, the denominator is out of 582 assessed products from 18 companies (ten generics and eight R&D pharmaceutical companies) with owned manufacturing sites and assessed at least one product.

By sector:

- Generics companies: 88% of products assessed at owned manufacturing sites for which assessment results were available met PNEC targets (398 of 453 products).
- R&D pharmaceutical: 69% of products assessed at owned manufacturing sites for which assessment results were available met PNEC targets (89 of 129 products).

**Over half (56%) of respondent companies that assessed products from their owned manufacturing sites against PNEC targets had all their products meet PNEC targets** (10 of 18 companies):

- Generics companies: 40% (4 of 10) that assessed products from their owned manufacturing sites against PNEC targets had all their products meet PNEC targets.
- R&D pharmaceutical: 75% (6 of 8) that assessed products from their owned manufacturing sites against PNEC targets had all their products meet PNEC targets.

**Less than half (44%) of respondent companies that assessed products from their owned manufacturing sites against PNEC targets had some of their products meet PNEC targets** (8 of 18 companies):

- Generics companies: 60% (6 of 10) that assessed products from their owned manufacturing sites against PNEC targets had some of their products meet PNEC targets.
- R&D Pharmaceutical companies: 25% (2 of 8) that assessed products from their owned manufacturing sites against PNEC targets had some of their products meet PNEC targets.

**No companies that assessed products from their owned manufacturing sites against PNEC targets had zero products meeting PNEC targets.**

Among the 19 companies that owned sites and assessed their products against PNEC (including the one company that undertook assessments but could not report on results), **the most common actions reportedly taken to ensure owned products met PNEC targets** (i.e. where half or more of the companies took a particular action) were:

- **Dry/vacuumed cleaning of product areas: 74% (n=14).**
- **Collecting equipment rinses and treating them separately: 68% (n=13).**
- **Performed Mass Balance for all compounds: 63% (n=12);** 32% (n=6) performed Mass Balance for *some* compounds.
- **Sampling and analysis for some compounds: 53% (n=10);** 21% (n=4) performed sampling and analysis for *all* compounds.
- Adding additional wastewater treatment technology (capital expense):32% (n=6).

- Adding additional wastewater treatment technology (revenue expense): 26% (n=5).
- No action: 0% (n=0).

'Other' actions taken (n=3) include completing mass balances for all compounds and making updates with more accurate information (i.e. river flow assessment), updates based on the AMRIA Standard and latest PNECs, sampling activity, treatability studies to assess wastewater treatment alternatives, and preliminary design for wastewater treatment systems.

## 4.4. Direct supplier sites overview

**Overall, there were 809 direct antibiotic manufacturing supplier sites**:

- 61% (n=497) of these were attributed to generics survey respondents
- 39% (n=312) of these were reported from R&D pharmaceutical companies. One R&D pharmaceutical company reported zero supplier sites.

**Out of the 21 companies with at least one direct antibiotic manufacturing supplier, over half (52%; four generics and seven R&D pharmaceutical companies) conveyed CAMF expectations to all their antibiotic manufacturing suppliers:**

- 38% of the companies had conveyed CAMF expectations to some direct suppliers (n=8; five generics and three R&D pharmaceutical companies), and 10% (n=2; one generics and one R&D pharmaceutical company) did not convey requirements to any of their supplier sites.
- For the companies that had conveyed CAMF expectations to some of their suppliers, the per cent of suppliers who had CAMF expectations conveyed to them varied from 27–90%, depending on the company. The mean percentage of a company's suppliers to whom they conveyed expectations was 74%.

**Companies conveyed CAMF expectations to supplier sites in various ways.** Over half of companies with direct supplier sites (58%; 11 out of 19 that conveyed expectations) conveyed expectations via verbal communication. Less frequent methods were as a requirement of a tender process (11%, n=2) and in a written supply contract (26%, n=5). Some companies conveyed expectations in other ways (74%, n=14), with written communication used fairly widely. Other methods of conveying expectations included using Tier 1 supplier awareness of a Supplier Code of Conduct, via mail and purchase orders, virtual training on CAMF, virtual and on-site audits, written communication and forwarding CAMF-related literature, the AMR survey dissemination, ESG questionnaire, questionnaires during selection phases of suppliers, other written or email information and assurance communications, and as part of wider supplier surveys and on-site EHS assessments.

**Overall, 50% of supplier sites had been assessed by audit again the CAMF criteria (405 of 809 sites); audit assessment of direct supplier sites against the CAMF criteria was more common for R&D pharma**ceutical **direct supplier sites than for generics sector direct supplier sites:**

- All R&D pharmaceutical supplier sites: 90% of direct suppliers were assessed against CAMF criteria for (281 of 312).

- All generics supplier sites: 25% of direct supplier sites were assessed against CAMF criteria (124 of 497).

**Nearly a quarter of companies with supplier sites assessed all of their sites against CAMF criteria; over half assessed some but not all direct supplier sites against CAMF criteria**. Of the 21 companies that reported at least one supplier site:

- Some 24% (n=5; two generics and three R&D pharmaceuticals) of companies assessed all their supplier sites against CAMF.
- Some 52% (n=11; six generics and five R&D pharmaceuticals) of companies assessed some but not all their supplier sites against CAMF.
- Some 24% (n=5; two generics and three R&D pharmaceuticals) did not assess any of their direct supplier sites against CAMF.

## 4.5. Direct supplier sites and CAMF assessement

**Some 16 companies assessed some or all of their supplier sites by audit against CAMF** criteria (eight R&D pharmaceutical and eight generics companies):

- A quarter of the companies (25%; 4 of 16) that assessed some or all of their supplier sites against CAMF criteria reported that all of the assessed sites fully met the CAMF requirements (this included three generics and one R&D pharmaceutical company).
- Nearly two-thirds of companies (63%; 10 of 16) that assessed some or all of their sites against CAMF criteria had some but not all assessed sites fully meeting them (including three generics and seven R&D pharmaceutical companies). The percentage of supplier sites fully meeting CAMF requirements varied widely among these ten companies, from 25–98% of supplier sites:
    - » Generics: 67% of companies (1 of 3) with at least some sites fully meeting CAMF criteria reported over half of their supplier sites fully met CAMF requirements.
    - » R&D pharmaceutical: 86% (6 of 7) of companies with at least some sites fully meeting CAMF criteria reported that half or more of their sites fully met CAMF requirements.
- For another two companies (two generics), none of their sites fully met CAMF requirements.

Of the 405 sites assessed, 277 fully met CAMF requirements (68%). At the site level, 53 of 124 sites (43%) for generics companies fully met CAMF criteria, and 224 of 281 sites (80%) for R&D pharmaceutical companies met CAMF criteria.

**Nearly two-thirds (63%, n=10) of the 16 companies that assessed some or all of their supplier sites by audit against CAMF criteria had some sites partially meeting CAMF criteria**, including four generics sector companies and six R&D pharmaceutical sector companies:

- The number of supplier sites partially meeting CAMF criteria varied widely across these companies, from 2–60%.

- Generics: 50% (2 of 4) of companies with some sites partially meeting CAMF criteria reported that at least half of supplier sites partially met CAMF requirements.
- R&D pharmaceutical: 17% (1 of 6) of companies with some sites partially meeting CAMF criteria reported that at least half of supplier sites partially met CAMF requirements.

**Six companies (38% of the 16 companies that assessed some or all of their sites against CAMF criteria) had some sites not meeting CAMF requirements** (this included three generics and three R&D pharmaceutical companies):

- The percentage of sites that did not meet CAMF requirements varied widely, ranging from 2–51%.
- None of the three generics companies reported over half of their supplier sites not meeting CAMF requirements, and one out of three R&D pharmaceutical (33%) reported over half of their supplier sites not meeting CAMF requirements.

Twelve companies had some sites either partially or not meeting CAMF requirements. Of the 16 companies that assessed their sites against CAMF, all sites were fully compliant with CAMF for four, meaning that the remaining 12 had some that partially or did not meet CAMF). Of these:

- Four companies (33%; one generics, three R&D pharmaceutical) intended to have all supplier sites meet CAMF requirements within a year.
- Three companies (25%, 3 R&D pharmaceutical) intended to have all supplier sites meet CAMF requirements within 2–3 years.
- One company intended to have all supplier sites within three years (0–1 and 2–3 years).
- Two companies intended to have all supplier sites meet CAMF between 2–5 years (2–3 and 4–5 years).
- Two companies had data issues with this question (i.e. either did not specify, or the number of products reported did not either partially or fully match the number of products in their response to the previous question).

## 4.6. Products manufactured at direct supplier sites and PNEC targets

**Some 816 products were manufactured at direct supplier sites. Of these, 55% (n=445) were reported to apply to direct suppliers of generics companies and 45% (n=371) were reported to apply to direct suppliers of R&D pharmaceutical companies.** *Note: This data applies to 20 companies with at least one direct supplier manufacturing at least one product. Twenty-one companies had direct supplier sites, but one did not have any direct supplier sites that manufactured products for them during the survey period.*

Overall, 19 companies with direct supplier sites (of 20 companies with direct supplier sites who manufactured at least one product) could provide data on the number of products assessed against PNEC. **Over half (53%) of antibiotic products from supplier sites were assessed against PNEC targets** (368 of 698 ):

- **Some 43% of products from direct suppliers to generics sector companies were assessed against PNEC targets** (193 of 445 products).
- **Some 69% of products from direct suppliers to R&D pharmaceutical companies were assessed against PNEC targets** (175 of 253 products).

Overall, 19 companies with direct supplier sites (of 20 with direct supplier sites who manufactured at least one product) could provide data on the number of products assessed against PNEC targets. Of these:

- **Just over a fifth (21%) of the companies assessed all their direct supplier products against PNEC targets** (n=4; one generics and three R&D pharmaceutical companies).
- **Nearly two-thirds (63%) of the companies assessed some of their direct supplier products against PNEC targets** (n=12; seven generics and five R&D pharmaceutical companies).
- **16% did not assess any of their supplier products against PNEC targets** (n=3; one generics and two R&D pharmaceutical companies).

**Of products manufactured at supplier sites and assessed against PNEC targets, 76% met PNEC targets** (281 of 368). This data applies to 16 companies that assessed all or some of their direct supplier products:

- **Overall, 86% of products from direct suppliers to R&D pharmaceutical companies that have been assessed met PNEC targets** (151 of 175).
- **A total of 67% of products from direct suppliers to generics companies that have been assessed met PNEC targets** (130 of 193).

**Nearly two-thirds (n=10, 63%) of the 16 companies who had products assessed against PNEC targets had all of their supplier site products meet PNEC targets** (n=10; four generics and six R&D pharmaceutical companies).

**Overall, 38% (n=6) of the 16 companies who had products assessed against PNEC targets had some of their supplier site products met PNEC targets** (n=6; four generics and two R&D pharmaceutical companies):

- The mean per cent of products from supplier sites that were assessed and met PNEC targets is 88%, ranging widely from 28–100%.

**The 20 companies that reported at least one antibiotic product manufactured at a direct supplier site undertook diverse actions to ensure that direct antibiotic manufacturing suppliers met the PNEC targets**. No single distinct action was taken by more than half of the companies responding, but notable actions taken by a third or more of the companies included:

- Providing technical guidance/toolkits to suppliers for performing mass balance: 45% (n=9).
- Reviewing/checking that their suppliers took corrective actions post-audit if such actions were needed 35% (n=7).
- Reviewing supplier Mass Balance: 35% (n=7) reviewed supplier Mass Balance for SOME but not ALL compounds, while 30% (n=6) reviewed supplier Mass Balance (for ALL compounds).
- No companies provided funding (beyond the supply contract) for a supplier(s) to do any of the above.
- Other responses (n=5) were provided on actions taken with narrative examples spanning setting up CAPAs and monitoring progress related to suppliers having zero liquid discharge facilities, discussions with suppliers on AMR and expectations during EHS Assessments following PSCI Principles and inviting suppliers to PSCI & company-specific PIE & AMR management training.

Of the seven companies that indicated in the previous question that they reviewed/checked that their suppliers took corrective actions post-audit:

- A total of 100% (n=7) reported that suppliers conducted dry/vacuum cleaning of production areas and suppliers collected equipment rinses and rated separately.
- Some 57% (n=4) responded that suppliers added additional wastewater treatment technology (revenue expense).

## ABOUT THE AMR INDUSTRY ALLIANCE

The AMR Industry Alliance is a coalition of over 100 biotechnology, diagnostic, generics and research-based biopharmaceutical companies and 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.

**amrindustryalliance.org**