amr INDUSTRY ALLIANCE
UNITED AGAINST ANTIMICROBIAL RESISTANCE

PROGRESS REPORT

AMR Industry Alliance 2021 Survey

ANNEX

February 2022

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.

Published January 2022

Annex A. Additional information on methodology

A.1. SURVEY PROTOCOL

CONSENT TO PARTICIPATE IN SURVEY

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

1. I confirm that I have read the information sheet on participation in this survey, including the privacy notice. *****

- ☐ Yes
- ☐ No

2. I confirm that I have been given the opportunity to consider the information, it has been made clear to me that I can ask clarification questions if needed and have had these answered satisfactorily (if applicable). *

- ☐ Yes
- ☐ No

3. I understand that my participation, on behalf of my company, is voluntary and that I am free to withdraw at any time without giving any reason, without being penalised in any way or my legal rights being affected. *

- ☐ Yes
- ☐ No

4. I agree, on behalf of my company, to the name of my organisation being listed as part of a list of organisations who were consulted for this project, in an appendix to the Progress Report. *****

- ☐ Yes
- ☐ No

5. I understand that the Progress Report will not publicly disclose information related to financial investments made by my company at the level of my company. Such data will be used to analyse investment levels at the level of a sector and Alliance overall and shall be deidentified and not individual company level. *****

- ☐ Yes
- ☐ No

6. If applicable to my sector (i.e. for R&D pharmaceuticals and generics companies), I understand that the Progress Report will not disclose information related to my company's compliance with the requirements of the Common Antibiotics Manufacturing Framework and PNEC targets at the level of my company. That data will be used to analyse compliance and achievements at the sector and Alliance level and shall be deidentified and not at company level. *

- [ ] Yes
- [ ] No
- [ ] Not applicable to my company/sector because we are a biotechnology/SME or diagnostics company

7. I understand that there are questions in the survey which ask for case examples and narrative information on our activities as they relate to AMR, which may be synthesised to give case examples in the Progress Report that are attributed to my company. I confirm, on behalf of my company, that I shall not disclose commercially sensitive or confidential information in my replies to those questions. *

- [ ] Yes
- [ ] No

8. I confirm, on behalf of my company, that deidentified answers (e.g. with a unique identifier linking questions e.g. Company 1, Company 2, Company 3) to the survey questions can be shared for the Secretariat's purposes with the individuals in the AMR-Industry Alliance Secretariat having a contractual mandate to manage the Alliance Secretariat. (Case examples may be attributable to your company as noted above) **

- [ ] Yes
- [ ] No

9. I agree to participate in the survey, on behalf of my company. **

- [ ] Yes
- [ ] No

Please enter your full name in the box below. **

Please enter today's date in the box below (dd/mm/yyyy) **

Company Profile

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

10. Please provide your company name *

11. Please provide the information below for the survey respondent in your company: Guidance: This refers to the contact details of the person who is overseeing survey completion and submitting the response on behalf of your company. This information will be treated confidentially by RAND Europe and the AMR Industry Alliance Secretariat – we are asking it in the case that we need to get in touch for any clarifications in relation to your submission *

Name *

Role *

Email *

12. Where do you have AMR-relevant business units located? (Tick all that apply) Guidance: For a table of the countries included in each region, please check the accompanying AMRIA 2021 Guidance Document. *

- ☐ Africa
- ☐ North and Central America
- ☐ South America
- ☐ South East Asia
- ☐ Europe
- ☐ Eastern Mediterranean/ Middle East
- ☐ Western Pacific
- ☐ Other (please specify):

13. Where are your company's activities related to tackling AMR located (e.g. manufacturing, sales, research, etc.)? (Tick all that apply) Guidance: This question is based on the assumption that a company may carry out some activities in locations where it doesn't have formal business units. For a table of the countries included in each region, please check the accompanying AMRIA 2021 Guidance Document. *

- [ ] Africa
- [ ] North and Central America
- [ ] South America
- [ ] South East Asia
- [ ] Europe
- [ ] Eastern Mediterranean/ Middle East
- [ ] Western Pacific
- [ ] Other (please specify): _____

Section 1: Research and Development (R&D)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑ *	☑	☑

**Generics companies were not asked some questions in this section. Relevant questions are noted below.*

Guidance for this section:

This section of the survey refers to your company's investment and activities in Research and Development (R&D) for AMR-relevant pathogens. It is divided into six sub-sections: A) Financial investment in AMR-relevant R&D; B) Nature of R&D activities; C) Influences on investment levels in AMR-relevant R&D, including those related to policy, regulatory and other factors; D) Discontinued AMR-relevant R&D; E) Data sharing/data exchange; and F) Learning from the COVID-19 pandemic.

We will be asking about the levels of your company's financial investment in two time periods: (a) financial year 2019 and (b) financial year 2020. The purpose of asking for levels of financial investments for both financial years is to capture investments since the last reporting timeframe for the AMR Industry Alliance survey. This will also allow us to understand changes over time, including the potential impacts of the COVID-19 pandemic on investment levels into AMR-relevant R&D activity.

For all other questions (i.e. those not related to levels of financial investment), the reporting timeframe should cover your activities since the last survey reporting round. In other words, the reporting timeframe is 1st July 2019 and 31st March 2021. This is important to make sure we capture progress since the last AMR Industry Alliance progress report.

For the scope of this survey, we consider AMR-relevant products and/or technologies as those related to combating AMR. This includes products and/or technologies that have an impact on the

spread of antibiotic-resistant "priority pathogens" as identified by the WHO's priority pathogen list and/or the CDC's AR Threats Report but is not confined to pathogens on these lists alone.

We recognise that some products and/or technologies that combat AMR in relation to bacterial and fungal infections may indirectly be related to viruses, having an impact on 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, RSV and other respiratory infections) are in scope. Similarly, diagnostics tests that help distinguish between viral and bacterial infections are in scope as long as you clearly explain in the related narrative survey questions how they are linked to AMR and why they are important for distinguishing between a viral and bacterial infection. There are questions in the survey which ask about the types of products and/or technologies your company invests in (e.g. antibiotics, antifungals, vaccines, non-traditional approaches and others, and this is detailed in the questions in the survey).

Both R&D related to new chemical entities and R&D related to new indications for existing products and/or technologies (including adapting existing formulations for AMR-relevant usage, new dosages, new delivery methods and new combinations of products) are within scope.

All stages of R&D (pre-licensure) are relevant.

Please focus on investments relevant in a human health context. R&D investments related to animal health are out of scope of this section of the survey.

When completing the survey, please refer to the AMRIA 2021 Survey Guidance document provided.

Section 1 Sub-section A: Financial investment in AMR-relevant R&D

	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
Applicable to	☑	☑ *	☑	☑

** Generics companies were not asked some questions in this sub-section. Relevant questions are noted below.*

Guidance:

In this sub-section, we will be asking about the levels of investment that your company has made into R&D activities for AMR-relevant products and/or technologies

14. How much did your company invest in R&D for AMR-relevant products and/or technologies in FY2019 and FY2020? (For each financial year, tick one of the options below) Guidance: For companies with investment levels over USD 20 million, you must provide a specific figure in USD, rounded to the nearest million in the comment box provided. For companies with

investment levels under USD 20 million, it is optional to provide a specific figure in USD in the comment box provided. *

	Less than USD 1 million	USD 1-5 million	USD 6-10 million	USD 11-15 million	USD 16-20 million	Over USD 20 million: please specify exact figure rounded to the nearest million in comment box
FY2019	☐	☐	☐	☐	☐	☐
FY2020	☐	☐	☐	☐	☐	☐

Please specify exact amount per year (i.e. for FY2019 and FY2020) rounded to the nearest million (required/mandatory if over USD 20 million):

15. [OPTIONAL] Please provide a percentage of your company's overall R&D investment in products and/or technologies at the following stages of development across your AMR-relevant R&D portfolio in FY2019 and FY2020. Guidance: Please ensure that the percentage column adds up to 100%

[NOTE: This question was not asked to Generics companies]

	FY2019	FY2020
Early discovery (e.g. target identification, lead identification, lead optimisation, etc.)		
Pre-clinical (e.g. early antimicrobial medicine or vaccine testing, proof of concept, prototype development, pilot/feasibility studies, etc.)		
Clinical Phase I (e.g. trials of antimicrobial medicines or vaccines, clinical trials for diagnostics or other technologies, etc. in phase I)		
Clinical Phase II (e.g. trials of antimicrobial medicines or vaccines, clinical trials for diagnostics or other technologies, etc. in phase II)		

	FY2019	FY2020
Clinical Phase III (e.g. trials of antimicrobial medicines or vaccines, clinical trials for diagnostics or other technologies, etc. in phase III)		
Other R&D aspects		

16. In comparison to FY2018, did your company's investment in R&D for AMR-relevant products and/or technologies in FY2019: (Tick one option) Guidance: For companies that replied to the 2020 progress report, you may consider referring to your data submitted for the 2018 financial year. *

- [ ] Increase substantially (defined as an increase of more than 10%)
- [ ] Increase somewhat (defined as an increase of less than 10%)
- [ ] Stay approximately the same (defined as less than 5% change between years)
- [ ] Decrease somewhat (defined as a decrease of less than 10%)
- [ ] Decrease substantially (defined as a decrease of more than 10%)

17. [OPTIONAL] Please provide the reasons for the change in your company's investment levels in R&D for AMR-relevant products and/or technologies in FY2019 and FY2020 (max. 250 words).

18. Current market conditions, among other factors, may influence investment in R&D for AMR-relevant products and/or technologies. Under the different market conditions presented below, how would your company respond? (Tick one option per market scenario) Guidance: Market conditions can relate to aspects of market viability and attractiveness related to, for example, pull factors such as pricing, reimbursement and time it takes for regulatory approval, but they can also relate to push factors such as those related to policy incentives that reduce the costs or risks of R&D (and hence reduce investment risks). *

[NOTE: This question was not asked to Generics companies]

	Decrease investment	Maintain level of investment	Increase investment
In the case that the market for AMR-relevant R&D activities remains unchanged (e.g. no new policy incentives are developed to decrease costs and risks of R&D or secure market viability and certainty)	☐	☐	☐
In the case that the market for AMR-relevant R&D activities improves (e.g. new policy incentives are developed to decrease costs and risks of R&D or secure market viability and certainty)	☐	☐	☐
In the case that the market for AMR-relevant R&D activities worsens (e.g. pressures to reduces prices further increase, requirements in procurement tenders become more complex)	☐	☐	☐

Section 1 Sub-section B: Nature of R&D activities

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑ *	☑	☑

**Generics companies were not asked some questions in this sub-section. Relevant questions are noted below.*

Guidance:

In this sub-section, we will enquire about the types of R&D your company has pursued in AMR-relevant R&D activities.

We are primarily interested in what your company has been doing since the last reporting period – i.e. in the time period between 1st July 2019 and 31st March 2021. We appreciate this may not directly map onto your financial year investment level reporting, and this will be noted as a caveat of the analysis when the progress report is being produced. The decision to ask about the nature of your activities in the 1st July 2019 to 31st March 2021 period was made as the key interest of the AMR Industry Alliance is in understanding activity since the last reporting period

19. What stages of R&D for AMR-relevant products and/or technologies did your company invest in during the time period between 1st July 2019 and 31st March 2021? (Please indicate the number of AMR-relevant products and/or technologies for each stage of R&D in which your company has invested) Guidance: You must provide a number in each line below. If your company did not invest in any stages of R&D for AMR-relevant products during the specified time period, please input 0. If an AMR-relevant product and/or technology has more than one indication, please count this as one product/technology and not as multiple products and technologies. Please report on the status of a product and/or technology as of 31st March 2021. Please note there are questions later in the survey where you can explain progression of products across the phases or discontinuation. *

[NOTE: This question was not asked to Generics companies]

Early discovery (e.g. target identification, lead identification, lead optimisation)	*
Pre-clinical (e.g. drug or vaccine testing in-cells and/or animals, proof-of concept, prototype development, pilot/feasibility studies)	*
Clinical: Phase I clinical trials	*
Clinical: Phase II clinical trials	*
Clinical: Phase III clinical trials	*
Clinical: Clinical trials stages for diagnostics and technologies such as beta testing, pivotal trials etc.)	*
Other (in the comment box below, please provide a brief description)	*

Please provide a brief description if “other” was selected above:

20. For what types of AMR-relevant products and/or technologies did your company invest in R&D in the time period between 1st July 2019 and 31st March 2021? (Please indicate the number of AMR-relevant products and/or technologies in each case) Guidance: You must provide a number in each line below. If your company did not invest in any type of AMR-relevant product and/or technology during the specified time period, please input 0. Please consider and report on a product that can have multiple indications as one product, not as multiple products separately for each indication. Similarly, if a diagnostic platform/technology comes with assays for many different pathogens, please report it as one diagnostic platform/technology. You can clarify the associated assays for different pathogens when answering the question. *

Antibiotics (e.g. novel antibiotics, adapting dosages for existing antibiotics, new combinations of existing products/compounds, new indications for existing products, new/adapted formulations for use in specific patient populations or new delivery methods)	*
Antifungals (e.g. novel antifungals, adapting dosages for existing antifungals, new combinations of existing products/compounds, new indications for existing products, new/adapted formulations for use in specific patient populations or new delivery methods)	*
AMR-relevant vaccines (e.g. novel vaccines, adapted dosage approaches, adapted delivery methods)	*
Non-traditional and novel approaches (e.g. live biotherapeutic product and/or technology, monoclonal antibody, microbiome modulators, biofilm dispersants, virulence inhibitors, immunomodulators, lysine, antibody-antibiotic conjugates): [free text]	*
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 (please specify in comment box below)	*

Please specify if 'Other' selected above:

21. [OPTIONAL] In the text box below, please provide information on AMR-relevant products and/or technologies that your company invested in R&D in the time period between 1st July 2019 and 31st March 2021, and that are NOT already listed in PEW's list of "Antibiotics Currently in Global Clinical Development" or PEW's list of "Non-traditional Products in Development to Combat Bacterial Infections". Please submit information for one product/technology at a time, labelling your replies for each product/technology, and answering questions a-g below for each. The word limit for the question is 300 words per product/technology. a) Name of the product/technology b) Was your activity related to this product/technology related to R&D on novel chemical entities, adapting dosages for existing products, new combinations of existing products/compounds, new indications for existing products, new/adapted formulations for use in specific patient populations or new delivery method;

novel technologies, repurposed/new applications of existing technologies? c) Stage of R&D d) Type of product/technology e) Pathogen(s) at which the product/technology is aimed f) Indications (i.e. the use of the same product/technology for more than one disease/infection). g) If the product/technology was developed in collaboration with an external organisation, who did you collaborate or partner with? Guidance: Please report on products/technologies that relate to bacteria and fungi, as well as viral products as defined in the scope of the survey that have not been previously reported by your company in the PEW's lists mentioned above. Please note the question focuses on the PEW's lists and not WHO list. This is because the most recent WHO list on products in clinical development was published in 2019 with source data that would cover only information up to and including 1st September 2019. However, if you would like to consult the WHO list as well to inform your answer, it can be accessed here. Please note that the information you provide may potentially be used as a case example in the progress report to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information. If you are unable to provide a reply due to commercial sensitivity, please answer with "commercially sensitive". Please consider and report on a product that can have multiple indications as one product, not as multiple products separately for each indication. Similarly, if a diagnostic platform/technology comes with assays for many different pathogens, please report it as one diagnostic platform/technology. You can clarify the associated assays for different pathogens when answering the question. Please check the AMRIA 2021 Survey Guidance document for guidance on how to respond. Example response: Product/technology 1: a) b) c) d) e) f) g)

22. What types of collaborations for AMR-relevant R&D did your company engage in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

[NOTE: This question was not asked to Generics companies]

- ☐ Partnerships with country-level government bodies
- ☐ Collaborations with existing public-private partnerships (e.g. Gavi, the Vaccine Alliance, Drugs for Neglected Diseases Initiative (DNDi)
- ☐ Partnerships with other international organisations (e.g. with WHO, European Centre for Disease Prevention and Control (ECDC), etc.)
- ☐ Partnerships with charity, non-governmental organisation (NGO) or foundation organisations
- ☐ Collaborations with academic institutions
- ☐ Collaborations with hospitals and medical laboratories
- ☐ Collaborations with other private sector/industry organisations (e.g. companies, industry associations)
- ☐ Not applicable – we did not collaborate with external organisations
- ☐ Other (please specify): ☐

23. At what stages in your product/technology development pathway do you establish the following (Please tick the most appropriate option (column) for each item (row)): Guidance: We are interested in understanding how early on during R&D, or post R&D do you begin thinking about and formulating plans for supply, expected volumes of your product/technology needed by the market, and developing your commercialisation plans. *

	Very early on in an R&D process - at preclinical stages	During Phase I clinical trials	During Phase II clinical trials	During Phase III clinical trials	After licensure	Not applicable
A supply plan for the product/technology to have in place if the product/technology is successfully developed and approved	☐	☐	☐	☐	☐	☐
Volume and demand forecasts	☐	☐	☐	☐	☐	☐
Commercialisation plans	☐	☐	☐	☐	☐	☐

Section 1 Sub-section C: Influences on investment levels in AMR-relevant R&D, including those related to policy, regulatory and other factors

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑ *	☑	☑

**Generics companies were not asked some questions in this sub-section. Relevant questions are noted below.*

Guidance:

In this sub-section we will enquire about the factors influencing your company's investment in R&D activities. This will help us understand wider challenges facing investment in AMR-relevant R&D.

We will also ask about the extent to which various incentives and conditions could influence your company's investment levels in AMR-relevant R&D in the future.

Finally, we will ask about how you have been engaging with the wider landscape in relation to helping influence the conditions (e.g. policy, regulatory, funding related etc.) that can affect your investment levels in AMR-relevant R&D.

24. On a scale of 1 to 4, to what extent did the following factors challenge your company's investment levels in R&D for AMR-relevant products and/or technologies in FY2019 and/or FY2020? We are considering the factors in the context of challenges. *****

[NOTE: This question was not asked to Generics companies]

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Lack of appropriate package of pull incentives in general	☐	☐	☐	☐	☐
Specific pull: Lack of advanced market commitments/ guaranteed purchase funds	☐	☐	☐	☐	☐

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Specific pull: Lack of appropriate valuation mechanisms specific	☐	☐	☐	☐	☐
Specific pull: Lack of appropriate reimbursement mechanisms	☐	☐	☐	☐	☐
Market viability concerns related to lack of clear and stable market size, uncertain prescriber and/or payer behaviours	☐	☐	☐	☐	☐
Historical sales volumes (e.g. low volumes as a challenge) influencing investments going forward	☐	☐	☐	☐	☐
Regulation challenge: High cost of the regulatory approval process	☐	☐	☐	☐	☐
Lack of appropriate push incentives for the development of AMR-relevant products and/or technologies (e.g. external funding support, tax credits on R&D)	☐	☐	☐	☐	☐

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
The availability of needed skills and capabilities for AMR-relevant R&D activities	☐	☐	☐	☐	☐
Inability to identify and/or form collaborations needed for R&D	☐	☐	☐	☐	☐
Risk of R&D/ scientific failure for AMR products/ technologies	☐	☐	☐	☐	☐
COVID-19 impact on challenging investments that can be made in AMR-relevant R&D	☐	☐	☐	☐	☐
Activities of our competitors as a challenge	☐	☐	☐	☐	☐
Other priorities in the company	☐	☐	☐	☐	☐
Other challenges (please specify in comment box below)	☐	☐	☐	☐	☐

Please specify challenges if 'Other' selected above

25. On a scale of 1 to 4, to what extent would the following instruments/incentives/conditions influence the likelihood of your company increasing investment levels in R&D for AMR-relevant products and/or technologies? *

[NOTE: This question was not asked to Generics companies]

	1 No influence is likely	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Improved package of pull incentives in general	☐	☐	☐	☐	☐
Improving valuation models for novel products and/or technologies specifically, to capture full societal benefit	☐	☐	☐	☐	☐
Changes in reimbursement models to support patient access to novel antibiotics	☐	☐	☐	☐	☐
Guaranteed purchase funds/advanced market commitments for AMR-relevant products/technologies	☐	☐	☐	☐	☐
Market entry awards (structured payments made to companies that successfully bring to market new antimicrobials)	☐	☐	☐	☐	☐
Transferrable patent exclusivity extensions	☐	☐	☐	☐	☐

	1 No influence is likely	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Waiving registration and evaluation fees for AMR-relevant products and/or technologies	☐	☐	☐	☐	☐
Greater streamlining and/or harmonisation of regulatory approval processes to make them more efficient	☐	☐	☐	☐	☐
Greater availability of external (e.g. public grant) funding	☐	☐	☐	☐	☐
Tax credits for AMR-relevant R&D activities	☐	☐	☐	☐	☐
Subscription based models where companies are paid a monthly fee to incentivise AMR-relevant R&D in exchange for health authorities securing access to innovations in advance of approval	☐	☐	☐	☐	☐
Bond-based incentives that mobilises long-term pledges from governments and other stakeholders to a finance facility, which in turn allows that facility to raise funding on the capital market in the form of investments	☐	☐	☐	☐	☐

	1 No influence is likely	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Other (please specify in comment box below)	☐	☐	☐	☐	☐

Please specify if 'Other' selected above

26. [OPTIONAL] In the time between 1st July 2019 and 31st of March 2021, what key factors facilitated (i.e. enabled) your company's investment in AMR-relevant R&D activity? (max. 300 words)

27. What actions, if any, did your company take between 1st July 2019 and 31st March 2021 to try to help improve the market conditions for AMR-relevant R&D investment? (Tick all that apply) *

[NOTE: This question was not asked to Generics companies]

- ☐ We engaged with efforts to test new payment models (e.g. outcome-based pricing, adaptive pricing and flexible pricing arrangements)
- ☐ We were involved with efforts to find improved and/or more innovative ways of assessing the value of new antimicrobials products and/or technologies
- ☐ We engaged with informing high-level discussions and global policy debates (e.g. on policy, regulatory and market related issues)
- ☐ We were involved in advocating for incentives (e.g. engagement with alliances such as the Global Antibiotic Research and Development Partnership (GARDP), the Biotech Companies in Europe Combating AntiMicrobial Resistance (BEAM) Alliance, the Antimicrobial Innovation Alliance (AIA) and Innovative Medicines Initiative (IMI) and/or industry efforts such as those of BIO, PhRMA, IFPMA .
- ☐ Not applicable (we did not take any actions in this space as a company)
- ☐ Other (please specify):

28. [OPTIONAL]: Please elaborate on the key actions/activities your company took to improve the market conditions for AMR-relevant R&D in the text box below. We strongly encourage you to please submit information related to one action/activity at a time, labelling your replies for each action/activity a-f. The word limit for this question is 500 words per action/activity. a) Brief description of the activity b) Product and/or technology to which it relates (if applicable). If not product/technology specific, put N/A) c) Pathogen(s) to which is relates (if applicable) d) Partners/collaborators in the activity (if applicable) e) Achieved outcomes and impacts to date f) Expected outcomes/impacts in the future (if they have not yet materialised) Guidance: Please note that the information you provide may potentially be used as a case example in the progress report, to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions. If you are unable to provide a reply due to commercial sensitivity, please answer with "commercially sensitive". An example response to this type of question is provided in the AMRIA 2021 Survey Guidance document. Please check the guidance before submitting your answer. Example response: Activity 1: a) b) c) d) e) f) Activity 2: a) b) c) d) e) f)

29. [OPTIONAL] How did the COVID-19 pandemic influence your investment in R&D for AMR-relevant products and/or technologies more generally? We strongly encourage you to reply to this optional question (Tick all that apply)

- ☐ Decreased the amount of available internal funding for our company to invest in R&D activities for AMR-relevant products and/or technologies
- ☐ Increased the amount of available internal funding for our company to R&D activities for AMR-relevant products and/or technologies
- ☐ Led to delays in R&D activities for AMR-relevant products and/or technologies (e.g. as we refocused our effort or priorities)
- ☐ Accelerated R&D activities for AMR-relevant products and/or technologies
- ☐ Led to improved financial incentives for R&D activities for AMR-relevant products and/or technologies in the wider external landscape (e.g. policy and regulation related)
- ☐ Led to a reduced attractiveness/less supportive financial incentives for R&D activities for AMR-relevant products and/or technologies in the wider external landscape (e.g. policy and regulation related)
- ☐ Led to new collaborations for R&D activities for AMR-relevant products and/or technologies
- ☐ Halted existing collaborations for R&D activities for AMR-relevant products and/or technologies
- ☐ Led to increased data sharing for R&D activities for AMR-relevant products and/or technologies
- ☐ Led to decreased data sharing for R&D activities for AMR-relevant products and/or technologies
- ☐ Did not influence our investment in R&D for AMR-relevant products and/or technologies
- ☐ Other (please specify): ☐

Section 1 Sub-section D: Discontinued AMR-relevant R&D

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

Guidance:

In this sub-section, we seek to understand whether your company discontinued any AMR-relevant R&D programmes in the time period between 1st July 2019 and 31st March 2021.

30. Did your company discontinue any AMR-relevant R&D programmes in the time period between 1st July 2019 and 31st March 2021? *

- [ ] Yes
- [ ] No

Section 1 Sub-section D: Discontinued products and/or technologies or R&D (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

31. What are the key reasons your company discontinued AMR-relevant R&D programmes between 1st July 2019 and 31st March 2021. (a) Please provide an overview of reasons in general.* (b) OPTIONAL: Please also provide a brief case example for a specific AMR-relevant R&D programme your company discontinued describing what programme was for, what pathogens it was targeting, at what stage of R&D did you discontinue the programme and why you discontinued the programme (500 word limit) Guidance: Please note that the information you provide may potentially be used as a case example in the progress report, to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions. If you are unable to provide a reply due to commercial sensitivity, please answer with "commercially sensitive". Please consider and report on a product that can have multiple indications as one product, not as multiple products separately for each indication. Similarly, if a diagnostic platform and/or technology comes with assays for many different pathogens, please report it as one diagnostic platform and/or technology. You can clarify the associated assays for different pathogens when answering the question. A list of the stages of R&D, as considered in this survey is provided in the AMRIA 2021 Survey Guidance document.

Section 1 Sub-section E: Data sharing/data exchange

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑		☑	☑

Guidance:

In this sub-section we will enquire about whether and how you facilitated data sharing and exchange with external organisations/individuals in the time period between 1st July 2019 and 31st March 2021, as it relates to AMR-relevant activities.

The types of data shared and exchanged can be diverse, for example data related to new drug targets, new compound leads, clinical trials, data relevant for regulatory aspects, off-patent antibiotics, manufacturing related activities, surveillance and epidemiological data, data related to stewardship activities or other. Data sharing and exchange can be through journal publications, conferences, websites and can be of diverse types such as qualitative, quantitative, code, etc. Although this sub-section of the survey has thus far focused mainly on R&D aspects of your activities, in order not to repeat questions unnecessarily in other sections of the survey we will be asking about a broader range of data sharing activities in this sub-section.

32. Did you facilitate data sharing and/or exchange of information related to R&D for AMR-relevant products and/or technologies in the time period between 1st July 2019 and 31st March 2021? (Tick one option) *

[NOTE: This question was not asked to Generics companies]

- ☐ Yes
- ☐ No

Section 1 Sub-section E: Data sharing/data exchange (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑		☑	☑

33. In which of the following ways did your company facilitate data exchange in relation to AMR- relevant activity in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

[NOTE: This question was not asked to Generics companies]

- [ ] Through journal publications (e.g. research papers, commentaries, editorials, published research protocols)
- [ ] Through publishing working paper and/or pre-prints
- [ ] Through conference contributions (e.g. writing conference abstracts, delivering presentations, speaking as part of expert panels)
- [ ] Through roundtables or workshops
- [ ] Through sharing research datasets and/or databases
- [ ] Through social media content and blogs
- [ ] Through our website content
- [ ] Through making our research protocols and analysis plans publicly available
- [ ] Through making pre-registration plans for products and/or technologies publicly available
- [ ] None of the above
- [ ] Other (please specify): _____

34. On what AMR-relevant activities did your company share data in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

[NOTE: This question was not asked to Generics companies]

- [ ] Data related to new drug targets relevant for AMR
- [ ] Data related to new compound leads relevant for AMR
- [ ] Data related to clinical trials design
- [ ] Data related to clinical trials results
- [ ] Data related to regulatory issues
- [ ] Data related to off-patent antibiotics
- [ ] Data related to manufacturing activities
- [ ] Data on epidemiology and/or surveillance
- [ ] Data relevant to stewardship activities
- [ ] None of the above
- [ ] Other (please specify): _____

Section 1 Sub-section F: Learning from the COVID-19 pandemic

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

35. [OPTIONAL] The COVID-19 pandemic has enabled research, in general, to happen in innovative ways, at pace and at scale. We have witnessed, for example, increased collaboration with tasks being done in parallel (e.g. R&D and scaling up manufacturing capacity) to tackle the pandemic, rapid mobilisation of resources, fast paced research, and accelerated regulatory approvals. In your opinion, is there any learning in terms of how the pandemic has been responded to that could be applicable and help support R&D for AMR-relevant products and/or technologies? Please share your reflections with us (max. 500 words)

Section 2: Access

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑ *	☑

**Biotech/SMEs were not asked some questions in this section. Relevant questions are noted below.*

Guidance for this section:

This section of the survey refers to your company's activities around issues related to access. This section of the survey is divided into four sub-sections: A) Availability and implementation of access strategies and/or plans to support access to AMR-relevant products and/or technologies; B) Addressing sustainable supply challenges for AMR-relevant products and/or technologies:

Supply chain resilience, stability and sustainability; C) Reducing the prevalence of substandard and/or falsified AMR-relevant products and/or technologies; and D) Removal of AMR-relevant products and/or technologies on the market

We are interested in better understanding how your company engages with efforts to improve access to AMR-relevant products and/or technologies (e.g. antimicrobial medicines, vaccines, diagnostic assays and platforms, etc.).

We are interested in multiple dimensions of access – for example in the context of: efforts related to registration of products and/or technologies with regulatory authorities; availability (e.g. supply chain continuity and stability for high quality products and/or technologies); affordability (e.g. the ability of markets to pay for and afford AMR-relevant products and/or technologies); ease of access (i.e. ease of access to available products by those who need them, for example through appropriate distribution channels, partnerships and health systems infrastructure and capacity); efforts related to collaborative access mechanisms; and efforts to advocacy on access-related issues.

For the scope of this survey, we consider AMR-relevant products and/or technologies as those related to combating AMR. This includes products and/or technologies that have an impact on the spread of antibiotic-resistant "priority pathogens" as identified by the WHO's priority pathogen list and/or the CDC's AR Threats Report but is not confined to pathogens on these lists alone.

We recognise that some products and/or technologies that combat AMR in relation to bacterial and fungal infections may indirectly be related to viruses, having an impact on 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, RSV and other respiratory infections) are in scope. Similarly, diagnostics tests that help distinguish between viral and bacterial infections are in scope as long as you clearly explain in the related narrative survey questions how they are linked to AMR and why they are important for distinguishing between a viral and bacterial infection. There are questions in the survey which ask about the types of technologies your company invests in (e.g. antibiotics, antifungals, vaccines, non-traditional approaches and others, and this is detailed in the questions in the survey).

The reporting timeframe should cover your activities since the last survey reporting round. In other words, the reporting timeframe is 1st July 2019 and 31st March 2021.

When completing the survey, please refer to the AMRIA 2021 Survey Guidance document provided.

Section 2 Sub-section A: Availability and implementation of access strategies or plans to support access to AMR-relevant products and/or technologies

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

Guidance:

In this sub-section, we will ask you about your company's access strategies and/or plans to support access to AMR-relevant products and/or technologies over the time period between 1st July 2019 and 31st March 2021.

36. In the time period between 1st July 2019 and 31st March 2021, did your company have access strategies and/or plan(s) to support access to AMR-relevant products and/or technologies? (Tick all that apply) Guidance: By strategies and/or plans, we refer to a formal plan of action designed to achieve an overall aim. It may be that your company has conducted activities to improve access to AMR-relevant products and/or technologies over the time period between 1st July 2019 and 31st March 2021 but does not have a formal strategy and/or plan. If this is the case, tick 'No' and you will be directed to questions that enquire about your activities in the absence of a formal strategy and/or plan. If you tick one of the yes options, please do not also tick the no option. *

- ☐ Yes, we have a general one that applies across all our products and/or technologies and it is publicly available
- ☐ Yes, we have a general one that applies across all our products and/or technologies but it is not publicly available
- ☐ Yes, we have one for specific products and/or technologies and it is publicly available
- ☐ Yes, we have one for specific products and/or technologies but it is not publicly available
- ☐ No, we do not have any access strategies and/or plan(s) to support access to AMR-relevant products and/or technologies

Section 2 Sub-section A: Availability and implementation of access strategies or plans to support access to AMR-relevant products and/or technologies (cont.)

	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
Applicable to	☑	☑	☑	☑

37. Do your company's access strategies and/or plans to support access to AMR-relevant products and/or technologies – as existing in the time period between 1st July 2019 and 31st March 2021 - apply to the following? (Tick all that apply) Guidance: In this question we are interested specifically in strategies and/or plans to support access, regardless of whether these have been acted upon. A question specific to activities to support access will be asked later. In responding to this question, please refer to the World Bank income classifications available in the AMRIA 2021 Survey Guidance document. *

- [ ] High income countries
- [ ] Upper middle income countries
- [ ] Lower middle income countries
- [ ] Low income countries
- [ ] None of the above/not specific to the income level of countries

38. Which of the following aspects did your company's access strategies and/or plans address in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

- [ ] Registration of products and/or technologies with regulatory authorities
- [ ] Availability (e.g. supply chain continuity and stability for high quality products/technologies and/or plans related to adapting existing products to new markets)
- [ ] Affordability (e.g. through general pricing, tiered pricing, compassionate use programmes, product donations, etc)
- [ ] Ease of access (e.g. working to ensure health systems capacity for appropriate access and use by those who need them, for example through appropriate distribution channels, support for health systems infrastructure)
- [ ] 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; collaborations around distribution)
- [ ] Advocacy (e.g. advocacy for effective regulation for approval processes and ensuring quality products and/or technologies; advocacy for the inclusion of new diagnostics tools in healthcare guidelines; advocacy related to appropriate use of products and/or technologies, etc.)
- [ ] None of the above
- [ ] Other (please specify): _____

Section 2 Sub-section A: Availability and implementation of access strategies or plans to support access to AMR-relevant products and/or technologies (cont.)

	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
Applicable to	☑	☑	☑	☑

39. We understand that your company did not have formal access strategies and/or plans to support access to AMR-relevant products and/or technologies in place in the time period between the 1st July 2019 and 31st March 2021. However, we are interested in understanding whether you engaged in activities to support access to AMR-relevant products and/or technologies during this timeframe- even in the absence of formal strategies and/or plans. Did your company engage in such activities? (Tick one of the following options)

- [ ] Yes
- [ ] No

Section 2 Sub-section A: Availability and implementation of access strategies or plans to support access to AMR-relevant products and/or technologies (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

40. For which of the following did your company undertake activities to support access to AMR-relevant products and/or technologies – in the timeframe between 1st July 2019 and 31st March 2021: (Tick all that apply) Guidance: In responding to this question, please refer to the World Bank income classifications available in the AMRIA 2021 Survey Guidance document. *

- [ ] High income countries
- [ ] Upper middle income countries
- [ ] Lower middle income countries
- [ ] Low income countries
- [ ] None of the above/not specific to the income level of countries

41. Which of the following aspects did the activities your company conduct to support access to AMR-relevant products and/or technologies in the time period between 1st July 2019 and 31st March 2021 address? (Tick all that apply) Guidance: We previously asked about whether you have plans covering the areas below. Now we are asking about whether you have actually implemented activities in the relevant areas. *****

- [ ] Registration of products and/or technologies with regulatory authorities
- [ ] Availability (e.g. supply chain continuity and stability for high quality products/ technologies and/or plans related to adapting existing products to new markets)

- [ ] Affordability (e.g. through general pricing, tiered pricing, compassionate use programmes, product donations, etc.)
- [ ] Ease of access (e.g. working to ensure health systems capacity for appropriate access and use by those who need them, for example through appropriate distribution channels, support for health systems infrastructure)
- [ ] 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; collaborations around distribution, etc.)
- [ ] Advocacy (e.g. advocacy for effective regulation for approval processes and ensuring quality products; advocacy for the inclusion of new diagnostics tools in healthcare guidelines, advocacy related to appropriate use of products and/or technologies, etc.)
- [ ] None of the above
- [ ] Other (please specify): _____

42. [OPTIONAL] Please briefly describe key relevant activities that your company has engaged with in the time period between 1st July 2019 and 31st March 2021 that relate to supporting access to AMR-relevant products and/or technologies, as that will enable us to better tell the story of your sector's activities, including through potential case examples. We strongly encourage you to please at minimum provide information for one key activity conducted to support access to AMR-relevant products and/or technologies during this timeframe. In the textbox below, please provide information for the key activities you would like to highlight. Please submit information for one activity at a time, labelling your replies for each activity a-g. The word limit for the question is up to 1000 words per activity. a) Activity area (i.e. registration, availability, affordability, ease of access, partnerships/collaborative access mechanisms, advocacy or other) b) Brief description of the activity c) Product and/or technology to which it relates (if applicable) d) AMR-relevant pathogen to which it relates (if applicable) e) External partners/ collaborators on the activity and their role (if applicable) f) Achieved outputs and impacts to date g) Expected outcomes/impacts in the future (if they have not yet materialised and not commercially sensitive) Guidance: Please note that the information you provide may potentially be used as a case example in the progress report to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions. If you are unable to provide a reply due to commercial sensitivity, please answer with "commercially sensitive". An example response to this type of question is provided in the AMRIA 2021 Survey Guidance document. Please check the guidance before submitting your answer. Example response: Activity 1: a) b) c) d) e) f) g) Activity 2: a) b) c) d) e) f) g)

Section 2 Sub-section A: Availability and implementation of access strategies or plans to support access to AMR-relevant products and/or technologies (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

43. On a scale of 1 to 4, to what extent were the following items barriers for your company in relation to enabling access to AMR-relevant products and/or technologies in the time period between 1st July 2019 and 31st March 2021. *

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Challenges to ensuring appropriate pricing and reimbursement influencing access activities	☐	☐	☐	☐	☐
High out-of-pocket expense for patients in some jurisdictions	☐	☐	☐	☐	☐
Challenges in supporting timely approval and registration of products influencing access	☐	☐	☐	☐	☐
Insufficient oversight/ regulation of manufacturing and supply chain leading to poor quality and/ or falsified products/ technologies	☐	☐	☐	☐	☐

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Insufficient supply chain resilience preventing consistent supply	☐	☐	☐	☐	☐
Lack of sufficient manufacturing capacity	☐	☐	☐	☐	☐
Lack of appropriate distribution channels	☐	☐	☐	☐	☐
Poor handling of antimicrobials (e.g. lack of cold-chain temperature control)	☐	☐	☐	☐	☐
Prescriber and/or payer behaviours which favour lower-cost older antimicrobials over novel ones that tackle AMR	☐	☐	☐	☐	☐
Inadequate stewardship around use of novel antimicrobials influencing access	☐	☐	☐	☐	☐
Lack of appropriate or sufficient partnering opportunities around expanding access and/or affordability	☐	☐	☐	☐	☐

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Other (please specify in comment box below)	☐	☐	☐	☐	☐

Please specify if 'Other' selected above

Section 2 Sub-section B: Addressing sustainable supply challenges for AMR-relevant products and/or technologies: Supply chain resilience, stability and sustainability

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

Guidance:

In this sub-section, we will ask you in more detail about the barriers and challenges specifically related to ensuring a sustainable supply of AMR-relevant products and/or technologies that your company has faced in the time period between 1st July 2019 and 31st March 2021. We will also seek to understand how they might be addressed.

44. In the time period between 1st July 2019 and 31st March 2021, did your company experience disruptions in the supply chain for AMR-relevant products and/or technologies? (Tick one of the following options) Guidance: By disruptions we mean events which disrupt the flow of product and/or technology supplies according to plan and can thus lead to shortages and impact on patient access. *

☐ Yes

☐ No

Section 2 Sub-section B: Addressing sustainable supply challenges for AMR-relevant products and/or technologies: Supply chain resilience, stability and sustainability (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

45. [OPTIONAL] What was the reason for the disruption and what did your company do to mitigate it? (Max. 500 words) Guidance: Please note that the information you provide may be used as a case example, so please do not disclose information you consider commercially sensitive

Section 2 Sub-section B: Addressing sustainable supply challenges for AMR-relevant products and/or technologies: Supply chain resilience, stability and sustainability (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

46. On a scale of 1 to 4, to what extent were the following items barriers and challenges to ensuring a sustainable and resilient supply of your AMR-relevant products and/or technologies in the time period between 1st July 2019 and 31st March 2021? *

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Difficulties in sourcing raw materials or other supplies reliably	☐	☐	☐	☐	☐
Lack of sufficient supplier diversity	☐	☐	☐	☐	☐
Lack of sufficient manufacturing capacity for our products	☐	☐	☐	☐	☐
Lack of appropriate distribution channels	☐	☐	☐	☐	☐
Lack of sufficient public-private collaboration around supply chain	☐	☐	☐	☐	☐
Lack of buffer stocks	☐	☐	☐	☐	☐
Lack of company insights to forecast demand and align it with supply	☐	☐	☐	☐	☐
Insufficient capacity and/or logistical hurdles for company to respond quickly to stock outs once they happen	☐	☐	☐	☐	☐
Regulatory hurdles following a disruption that challenge recovery	☐	☐	☐	☐	☐

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Pricing and reimbursement issues influencing how supply chains are managed	☐	☐	☐	☐	☐
Other (please specify in comment box below) (max. 100 words)	☐	☐	☐	☐	☐

Please specify if 'Other' selected above

47. [OPTIONAL] Please describe key relevant activities that your company has engaged in, in the time period between 1st July 2019 and 31st March 2021, which seek to improve supply chain resilience and sustainability. This will enable us to better tell the story of your sector's activities, including through potential case examples. We strongly encourage you to please at minimum provide information for one key activity related to actions your company has taken in this space. In the textbox below, please provide information for the key activities you would like to highlight. Please submit information for one activity at a time, labelling your replies for each activity a-f. The word limit for the question is up to 500 words per activity: a) Brief description of the activity b) Product and/or technology to which it relates (if relevant) c) AMR-relevant pathogen to which it relates (if relevant) d) External partners/collaborators on the activity and their role e) Outcomes/impacts achieved to date f) Expected future outcomes/impacts (if they have not yet materialised) Guidance: Please note that the information you provide may potentially be used as a case example in the progress report to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions. If you are unable to provide a reply due to commercial sensitivity, please answer with "commercially sensitive". An example response to this type of question is provided in the AMRIA 2021 Survey Guidance document, along with. Please check the guidance before submitting your answer. Example response: Activity 1: a) b) c) d) e) f) Activity 2: a) b) c) d) e) f)

Section 2 Sub-section C: Reducing the prevalence of substandard and/or falsified AMR-relevant products and/or technologies

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		☑

Guidance:

In this sub-section we will ask you about measures in place to reduce the prevalence of substandard and/or falsified AMR-relevant products and/or technologies.

48. Which of the following measures did your company have in place to help reduce the prevalence of substandard and falsified AMR-relevant products/technologies in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

[NOTE: This question was not asked to Biotech/SME companies]

- ☐ Enhancing product safety through packaging (e.g. tamper proof) and serialization
- ☐ Raising awareness about the risks of using substandard and falsified products and/or technologies (e.g. diagnostic tests) related to AMR pathogens
- ☐ Monitoring across product value chains to increase inspection coverage, monitor distribution channels, and improve surveillance of distributors and repackagers
- ☐ Introduce or improve inspection coverage
- ☐ Monitoring distribution channels
- ☐ Introduce or improve surveillance of distributors and repackagers
- ☐ Establishing counterfeit management teams
- ☐ Improving quality management systems and controls
- ☐ Working with healthcare community, regulators and law enforcement agencies to raise awareness of counterfeiting of diagnostic and biopharmaceutical products
- ☐ Not applicable - we do not have measures in place to reduce the prevalence of substandard and falsified products related to AMR pathogens
- ☐ Other (please specify) (max 100 words): ☐

49. [OPTIONAL] Please describe key relevant activities that your company has engaged in, in the time period between 1st July 2019 and 31st March 2021 to help reduce the prevalence of substandard and falsified AMR-relevant products/technologies, as that will enable us to better tell the story of your sector's activities, including through potential case examples. We

strongly encourage you to please at minimum provide information for one key activity related to measures your company has taken in this space. Please submit information for one activity at a time, labelling your replies for each activity a-f in the text box below. The word limit for the question is up to 500 words per activity: a) Brief description of the activity b) Product and/or technology to which it relates (if relevant) c) AMR-relevant pathogen to which it relates (if relevant) d) External partners/collaborators on the activity and their role (if applicable) e) Outcomes/impacts achieved to date f) Expected future outcomes/impacts (if they have not yet materialised and are not commercially sensitive) Guidance: Please note that the information you provide may potentially be used as a case example in the progress report to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions. If you are unable to provide a reply due to commercial sensitivity, please answer with "commercially sensitive". An example response to this type of question is provided in the AMRIA 2021 Survey Guidance document, along with. Please check the guidance before submitting your answer. Example response: Activity 1: a) b) c) d) e) f) Activity 2: a) b) c) d) e) f)

[NOTE: This question was not asked to Biotech/SME companies]

Section 2 Sub-section D: Removal of AMR-relevant products and/or technologies on the market

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

50. Did your company remove from the market any AMR-relevant products and/or technologies in the time period between 1st July 2019 and 31st March 2021? (Tick one of the options) *

- ☐ Yes
- ☐ No

Section 2 Sub-section D: Removal of AMR-relevant products and/or technologies on the market (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

51. What are the key reasons for which your company removed AMR-relevant products and/or technologies from the market (i.e. removed post-licensure)? (a) Please provide an overview of the reasons in general.* (b) OPTIONAL: Please also provide a brief case example for a specific product and/or technology that was removed from the market (i.e. removed post-licensure), what indication the product was for and why it was removed from the market. The word limit for the question is up to 500 words per product and/or technology.

Section 3: Appropriate use and stewardship of antimicrobials

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑ *	☑

**Biotech/SMEs were not asked some questions in this section. Relevant questions are noted below.*

Guidance for this section:

This section of the survey refers to your company's activities around appropriate use and stewardship. This section of the survey is divided into four sub-sections: A) Supporting appropriate use and stewardship; B) Collecting and sharing surveillance data; C) Promoting stewardship through education, awareness raising and through aligning promotional activities

with stewardship efforts; and D) Promoting responsible animal use of AMR-related products and/or technologies.

This section of the survey seeks to understand the different ways in which AMR Industry Alliance members are engaging with appropriate use and stewardship-related activities, all of which are important efforts to ensure that patients receive appropriate antimicrobial therapy.

The survey refers to activities and/or plans that have taken place between 1st July 2019 and 31st March 2021.

Consistent with the definitions used by the World Health Organization (WHO) and the Center for Disease Control and Prevention (CDC), the Alliance defines appropriate use of antimicrobials as: "The right patient receiving the right drug at the right dose in the right formulation at the right time for the right duration for the right pathogen and site of infection." (AMR Industry Alliance 2020 Progress Report, p. 66)

The Alliance defines antimicrobial stewardship as: "Multidisciplinary measures to systematically ensure appropriate use of products that may be taken at all levels of the global system" (AMR Industry Alliance 2020 Progress Report, p. 111).

Please focus on activities and/or plans relevant in a human health context in answering the questions for this section of the survey, unless otherwise specified. Most of the questions are being asked in the context of human health. Activities and/or plans related to animal health are covered by two questions at the end of this survey.

When completing the survey, please refer to the AMRIA 2021 Survey Guidance document provided.

Section 3 Sub-section A: Supporting appropriate use and stewardship

	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
Applicable to	☑	☑	☑	☑

Guidance:

In this sub-section, we will ask about any strategy and/or plan(s) that your company has developed to promote appropriate use and stewardship of antimicrobials. Where plans have not been established, we will also ask about whether your company is engaged in any activities to promote appropriate use and stewardship, even if you do not have a formal plan.

It may be that the appropriate use and stewardship strategy and/or plan(s) that your company had in place during the time period between 1st July 2019 and 31st March 2021 cover a broader time period than this. If this is the case, please report on all relevant strategies, plan(s) and/or activities as long as the strategy and/or plan(s) were active and/or the activities partly implemented during the reporting timeframe.

By strategies and/or plans, we refer to a formal plan of action designed to achieve an overall aim. It may be that your company has conducted activities related to appropriate use and stewardship over the time period between 1st July 2019 and 31st March 2021 but does not have a formal strategy and/or plan. If this is the case, tick 'No' and you will be directed to questions that enquire about your activities in the absence of a formal strategy and/or plan.

52. In the time period between 1st July 2019 and 31st March 2021, did your company have an appropriate use and stewardship strategy and/or plan(s) in place for AMR-relevant products and/or technologies? (Tick one option) *

- ☐ Yes, and it is publicly available
- ☐ Yes, but it is not publicly available
- ☐ No
- ☐ Not applicable, we did not engage in initiatives to promote appropriate antimicrobial use and good stewardship as it does not apply to our business model

Section 3 Sub-section A: Supporting appropriate use and stewardship (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

53. Does your company's strategy and/or plan(s) for appropriate use and stewardship for AMR-relevant products and/or technologies apply to the following? (Tick all that apply) Guidance: In responding to this question, please refer to the World Bank income classifications available in the AMRIA 2021 Survey Guidance document. *****

- ☐ High income countries
- ☐ Upper middle income countries
- ☐ Lower middle income countries
- ☐ Low income countries
- ☐ None of the above/not specific to the income level of countries

54. For which of the categories below did your company implement appropriate use and stewardship strategy and/or plan(s) in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *****

- [ ] Antibiotics
- [ ] Anti-fungals
- [ ] Vaccines related to AMR pathogens
- [ ] Biologics
- [ ] Diagnostics
- [ ] Other (please specify): _____

55. At what stages in your product and/or technology development pathway do you establish an appropriate use and stewardship plan for AMR-relevant products/technologies? (Tick the option that best applies to most cases for your products and technologies) *****

- [ ] Very early on in R&D process at preclinical stages
- [ ] During phase I clinical R&D stages
- [ ] During phase II clinical R&D stages
- [ ] During phase III clinical R&D stages
- [ ] Only after R&D stages are completed
- [ ] The stage at which it is considered varies across different products/technologies
- [ ] We do not establish this

56. In the time period between 1st July 2019 and 31st March 2021, which of the following areas did your company's appropriate use and stewardship strategy and/or plan(s) address? (Tick all that apply) *

- [ ] Supporting infection prevention and control (IPC) through activities related to promoting good hygiene, water and sanitation measures
- [ ] Supporting prevention through vaccines
- [ ] Supporting early, appropriate and/or expanded use of diagnostics to prevent antimicrobial misuse
- [ ] Generating evidence to support appropriate use and stewardship
- [ ] Collecting and/or sharing surveillance data
- [ ] Supporting appropriate use and stewardship through education and awareness-raising activities
- [ ] Efforts to align antimicrobial product and/or technology promotion activities to AMR stewardship
- [ ] Funding antimicrobial stewardship programmes delivered by others external to the company
- [ ] None of the above

☐ Other area (please state): _____

57. In the time period between 1st July 2019 and 31st March 2021, did your company measure the effects (e.g. outcomes or impacts) of its appropriate use and stewardship strategy and/or plan(s)? (Tick one option) Guidance: By outcomes, we refer to shorter-term changes that can be said to occur as a direct result of appropriate use and stewardship plans and associated activities. By impacts, we refer to broader societal-level changes that may be viewed as a result of such outcomes. For example, an outcome may be increased uptake of the pneumococcal vaccine and the impact of this would be decreased cases of pneumococcal disease. *

☐ Yes

☐ No

Section 3 Sub-section A: Supporting appropriate use and stewardship (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

58. We understand that your company did not have an appropriate use and stewardship strategy and/or plan(s) for AMR-relevant products and/or technologies in place between the 1st July 2019 and 31st March 2021. However, we are interested in understanding whether you engaged in any appropriate use and stewardship activities even in the absence of a formal strategy and/or plan(s). Did you engage in such activities in the time period between 1st July 2019 and 31 March 2021? (Tick one option) *

☐ Yes

☐ No

☐ Not applicable, we did not engage in initiatives to promote appropriate antimicrobial use and good stewardship as it does not apply to our business model

Section 3 Sub-section A: Supporting appropriate use and stewardship (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

59. For which of the following did your company undertake appropriate use and stewardship activities for AMR-relevant products and/or technologies in the time period between 1st July 2019 and 31st March 2021: (Tick all that apply) Guidance: In responding to this question, please refer to the World Bank income classifications available in the AMRIA 2021 Survey Guidance document. *

- ☐ High income countries
- ☐ Upper middle income countries
- ☐ Lower middle income countries
- ☐ Low income countries
- ☐ None of the above/not specific to the income level of countries

60. For which of the categories below did your company conduct activities related to appropriate use and stewardship in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

- ☐ Antibiotics
- ☐ Anti-fungals
- ☐ Vaccines related to AMR pathogens
- ☐ Biologics
- ☐ Diagnostics
- ☐ Other (please specify): _____

61. At what stages in your product and/or technology development pathway do you begin to consider appropriate use and stewardship activity needs for AMR-relevant products and/or technologies? (Tick the option that best applies to most cases for your products and technologies) *

- ☐ Very early on in R&D process at preclinical stages
- ☐ During phase I clinical R&D stages
- ☐ During phase II clinical R&D stages

- [ ] During phase III clinical R&D stages
- [ ] Only after R&D stages are completed
- [ ] The stage at which it is considered varies across different products/technologies
- [ ] We do not establish this

62. In the time period between 1st July 2019 and 31st March 2021, which of the following areas did your appropriate use and stewardship activities address: (Tick all that apply) *

- [ ] Supporting infection, prevention and control (IPC) through activities related to promoting good hygiene, water and sanitation measures
- [ ] Supporting prevention through vaccines
- [ ] Supporting early, appropriate and/or expanded use of diagnostics to prevent antimicrobial misuse
- [ ] Generating evidence to support appropriate use and stewardship
- [ ] Collecting and/or sharing surveillance data
- [ ] Supporting appropriate use and stewardship through education and awareness raising activities
- [ ] Efforts to align antimicrobial product and/or technology promotion activities to AMR stewardship
- [ ] Reducing uncontrolled use (including over the counter and non-prescription internet sales)
- [ ] Funding antimicrobial stewardship programmes delivered by others external to the company
- [ ] None of the above
- [ ] Other area (please state): _____

63. In the time period between 1st July 2019 and 31st March 2021, did your company measure the effects (e.g. outcomes or impacts) of its appropriate use and stewardship activities? (Tick one option) Guidance: By outcomes, we refer to shorter-term changes that can be said to occur as a direct result of appropriate use and stewardship activities. By impacts, we refer to broader societal-level changes that may be viewed as a result of such outcomes. For example, an outcome may be increased uptake of the pneumococcal vaccine and the impact of this would be decreased cases of pneumococcal disease. *

- [ ] Yes
- [ ] No

64. [OPTIONAL] Please provide further information on the types of appropriate use and stewardship activities you engage with in the text box below. Briefly describe key relevant activities that relate to appropriate use and stewardship that your company has engaged with in the time period between 1st July 2019 and 31st March 2021, as that will enable us to better tell the story of your sector's activities, including through potential case examples. We strongly encourage you to please at minimum provide information for one key activity conducted during this timeframe. Please submit information for one activity at a time, labelling your replies for each activity a-f. The word limit for the question is up to 500 words per activity: a) Brief description of the activity b) Product and/or technology to which it relates (if applicable) c) AMR pathogen to which is relates (if applicable) d) Partners/collaborators on the activity (if applicable) e) Achieved outputs and impacts to date f) Expected outcomes/impacts in the future (if they have not yet materialised Guidance: Please note that the information you provide may potentially be used as a case example in the progress report, to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions. An example response to this type of question is provided in the AMRIA 2021 Survey Guidance document, along with. Please check the guidance before submitting your answer. Example response: Activity 1: a) b) c) d) e) f) Activity 2: a) b) c) d) e) f)

Section 3 Sub-section B: Collecting and sharing surveillance data

	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
Applicable to	☑	☑	☑	☑

Guidance:

In this sub-section, we will ask about any efforts your company has undertaken to collect surveillance data relating to AMR in the time period between 1st July 2019 and 31st March 2021. We will also ask about the extent to which your company has shared surveillance data externally, and with whom it shared this data.

The types of surveillance data collected by companies may vary widely. As some examples, collected data may include antimicrobial sensitivity data, antimicrobial prescription data, resistance trends data, resistance mechanisms data, outbreak data, and post-market surveillance data relating to appropriate use.

65. Did your company collect any type of surveillance data in the time period between 1st July 2019 and 31st March 2021? (Tick one option) *

- ☐ Yes
- ☐ No
- ☐ Not applicable, we did not collect surveillance data as it does not apply to our business model

Section 3 Sub-section B: Collecting and sharing surveillance data (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

66. What type of surveillance data did your company collect in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

- ☐ Antimicrobial sensitivity data (i.e. the ability of an antimicrobial to inhibit the growth or promote death of a microorganism)
- ☐ Antimicrobial prescription data
- ☐ Resistance trends data
- ☐ Resistance mechanisms data
- ☐ Outbreak data
- ☐ None of the above
- ☐ Other (please specify): _____

67. What level of surveillance data did your company collect in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

- ☐ Pathogen level – species (e.g. Pseudomonas aeruginosa)
- ☐ Pathogen level – genus (e.g. Campylobacter spp.)
- ☐ Hospital level

- [ ] In-country regional level
- [ ] Country level
- [ ] None of the above
- [ ] Other (please specify): _____

68. Did your company share surveillance data externally in the time period between 1st July 2019 and 31st March 2021? (Tick one option) *

- [ ] Yes
- [ ] No

Section 3 Sub-section B: Collecting and sharing surveillance data (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

69. With which of the following did your company share surveillance data in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

- [ ] Healthcare professionals (HCPs)
- [ ] Healthcare authorities (national or local)
- [ ] Other private sector companies
- [ ] International organisations
- [ ] None of the above
- [ ] Other (please specify): _____

70. How did your company share surveillance data externally in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

- [ ] Through company-owned open access database or program
- [ ] Through company-owned licenced database or program
- [ ] Provided data to external open access databases
- [ ] Through peer-reviewed publications

- [ ] Through white paper publications (e.g. policy documents or reports that aim to provide evidence for strategic direction)
- [ ] Through presentations at conferences
- [ ] Through face-to-face meetings or workshops
- [ ] None of the above
- [ ] Other (please specify): _____

71. [OPTIONAL] If you have shared surveillance data externally, and in light of your reply to the previous question, we strongly encourage you to please provide some further information in the text box below, as it applies to your surveillance data sharing activities in the timeframe between 1st July 2019 and 31st March 2021. This will enable us to better tell the story of your sector's activities, including through potential case examples. Please provide information for at least one key data sharing activity conducted during this timeframe. In the text box below, please provide information for all the activities/mechanisms you would like to highlight. Please submit information for one activity/mechanism at a time, labelling your replies for each activity a-f. The word limit for the question is 500 words per activity/mechanism a) Product and/or technology name related to your surveillance data sharing activity (if applicable) b) Type of surveillance data shared c) Purpose of the surveillance data sharing activity d) Partners with whom the data was shared e) Achieved outcomes and impacts to date f) Expected outcomes/ impacts to date (if they have not yet materialised) Guidance: Please note that the information you provide may potentially be used as a case example in the progress report, to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions. An example response to this type of question is provided in the AMRIA 2021 Survey Guidance document, along with. Please check the guidance before submitting your answer. Example response: Activity/mechanism 1: a) b) c) d) e) f) Activity/mechanism 2: a) b) c) d) e) f)

Section 3 Sub-section C: Promoting stewardship through education, awareness raising and through aligning promotional activities with stewardship efforts

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		☑

Guidance:

In this sub-section, we will ask about your company's involvement in efforts to strengthen appropriate use and stewardship through education and awareness raising activities during the time period between 1st July 2019 and 31st March 2021. This sub-section will also ask about the extent to which your company aligns its pharmaceutical promotion activities with the goal of advancing appropriate use and stewardship.

72. Was your company engaged in initiatives that helped to educate and/or raise awareness about appropriate antimicrobial use and stewardship good practice in the time period between 1st July 2019 and 31st March 2021? (Tick one option) *

[NOTE: This question was not asked to Biotech/SME companies]

- ☐ Yes
- ☐ No
- ☐ Not applicable, we did not engage in initiatives to promote appropriate antimicrobial use and good stewardship as it does not apply to our business model

Section 3 Sub-section C: Promoting stewardship through education, awareness raising and through aligning promotional activities with stewardship efforts (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		☑

73. Which of the following stakeholder groups did your company seek to help educate or raise awareness amongst in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

[NOTE: This question was not asked to Biotech/SME companies]

- [ ] Healthcare professionals (individuals)
- [ ] Healthcare provider organisations (e.g. hospitals, primary care organisations)
- [ ] Patients and/or caregivers
- [ ] General public
- [ ] None of the above
- [ ] Other (please specify): _____

74. How did your company support appropriate use and stewardship through education, awareness-raising and/or efforts to align promotional activities with stewardship efforts in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *****

[NOTE: This question was not asked to Biotech/SME companies]

- [ ] Generating real-world evidence (i.e. clinical evidence regarding the usage and potential benefits or risks of a medical product and/or technology)
- [ ] Supporting investigator-initiated studies
- [ ] Pursuing additional post-approval indications (e.g. tailoring dosages for paediatric patients or developing easier-to-use formulations)
- [ ] Messaging on drug packaging to encourage patients to complete antimicrobial courses
- [ ] Developing and using software (e.g. chatbots) or other tools to improve patient adherence to antimicrobial therapy
- [ ] Developing software to help inform and support decision making on AMR prescribing
- [ ] Developing materials that explain AMR risks and key stewardship principles
- [ ] Distributing education and awareness raising materials and/or conducting education and awareness-raising activities (e.g. for hospitals or healthcare facilities, community settings, conferences)
- [ ] Social media campaigns
- [ ] Deploying diagnostics for pathogen identification
- [ ] Deploying diagnostics for antimicrobial susceptibility/resistance
- [ ] None of the above
- [ ] Other (please specify): _____

75. Did your company use any of the following strategies to ensure the quality of your educational or awareness raising materials in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *****

[NOTE: This question was not asked to Biotech/SME companies]

- [ ] Employ legal, compliance and internal quality reviews of the material
- [ ] Subject educational materials for stewardship activities to external peer review
- [ ] We do not have quality assurance processes in place for our educational or awareness raising materials
- [ ] Other measures to ensure quality of educational or awareness raising materials (please specify): _____

76. Did your company use any of the following strategies to mitigate potential conflicts of interest that may arise in engagements with healthcare providers and other stakeholders, in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

[NOTE: This question was not asked to Biotech/SME companies]

- [ ] Partnered with NGOs, educational organisations and/or independent experts to develop educational content
- [ ] Removed product and/or technology branding
- [ ] Refrained from the use of incentives (financial or other) to promote participation in AMR-related events
- [ ] We do not have strategies to mitigate potential conflicts of interest
- [ ] Other (please specify): _____

77. What initiatives did your company implement in the time period between 1st July 2019 and 31st March 2021 to ensure pharmaceutical promotional practices are consistent with the goal of advancing appropriate use and stewardship? (Tick all that apply) *

[NOTE: This question was not asked to Biotech/SME companies]

- [ ] We reviewed promotional activities against antimicrobial stewardship goals
- [ ] We included AMR-related educational materials, workshops, campaigns, and in-house training for healthcare professionals in relevant product and/or technology promotion activity
- [ ] We engaged in sharing risk and benefit assessments of relevant products and/or technologies with regards to AMR and appropriate use and stewardship with healthcare professionals
- [ ] We engaged in evaluating promotional materials against WHO, CDC, and/or other guidelines
- [ ] We reviewed sales representatives' incentive scheme, for example, by removing volume-based financial incentives for antimicrobial sales teams
- [ ] We have not yet done any activities in this space but are planning to review our promotional activities against antimicrobial stewardship goals
- [ ] Other (please specify): _____

78. [OPTIONAL] Please expand on any particular initiative that your company implemented in the time period between 1st July 2019 and 31st March 2021 to ensure pharmaceutical promotional practices were consistent with the goal of advancing appropriate use and stewardship that you would like to highlight (max 500 words). Guidance: Please note that the information you provide may potentially be used as a case example in the progress report, to show sector contributions. Please therefore be mindful of not disclosing commercially sensitive information – i.e. only provide information which you are happy to be used in the report to help us demonstrate your activities and contributions .

[NOTE: This question was not asked to Biotech/SME companies]

Section 3 Sub-section D: Promoting responsible animal use of AMR-relevant products and/or technologies

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		☑

Guidance:

In this sub-section, we ask about your company's involvement in the development of AMR-related products for animal use, as well as any efforts your company has undertaken to promote the responsible use of AMR-related products and/or technologies in animals. While focusing on human health, the Alliance recognises the importance of promoting responsible use of AMR-related products and/or technologies in animals as part of a 'One Health' approach to tackling AMR.

79. Did your company develop or commercialize products and/or technologies that are licensed for animal use in the time period between 1st July 2019 and 31st March 2021? (Tick one option) *

[NOTE: This question was not asked to Biotech/SME companies]

- ☐ Yes
- ☐ No

Section 3 Sub-section D: Promoting responsible animal use of AMR-relevant products and/or technologies (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		☑

80. How did your company promote responsible and judicious use of AMR-relevant products and/or technologies in animals in the time period between 1st July 2019 and 31st March 2021? (Tick all that apply) *

[NOTE: This question was not asked to Biotech/SME companies]

- ☐ Setting corporate policies on animal welfare
- ☐ Commercialising susceptibility tests for veterinary use
- ☐ Developing vaccinations in line with a One Health approach that can minimize the need for antibiotics
- ☐ Partnering with farmers and veterinarians to promote vaccination and the appropriate use and stewardship of antibiotics
- ☐ Collaborating with animal health and environmental organisations
- ☐ Other (please specify): _____

81. [OPTIONAL] Please expand on ways in which your company promoted responsible and judicious use of AMR-relevant products and/or technologies in animals in the time period between 1st July 2019 and 31st March 2021. The word limit for the question is up to 250 words.

[NOTE: This question was not asked to Biotech/SME companies]

Section 4: Manufacturing and the environment

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		

Guidance

This section of the survey refers to your company's activities around controlling antibiotic discharge into the environment. This section is divided into three sub-sections: A) Assessing own sites and products against the criteria in the Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentration (PNEC) targets; B) Conveying expectations of the Common Antibiotic Manufacturing Framework to direct suppliers; and C) Assessing direct supplier sites and products against the criteria in the Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentration targets.

In this section of the survey, we will be asking about the steps your company has taken to control antibiotic discharge into the environment through its manufacturing and supply chain processes.

The section includes questions regarding manufacturing processes performed in-house ("own sites") and through third-party manufacturers (at "direct supplier sites").

By own antibiotic manufacturing sites, we mean sites under direct control or ownership of the company in which an antibiotic active pharmaceutical ingredient (API) and/or drug product (i.e. formulated products) are manufactured.

By direct antibiotic manufacturing suppliers, we mean sites outside of the direct control or ownership of the company that supply an Alliance member company with an antibiotic API and/or drug product (i.e. formulated products). The scope of the survey is on direct suppliers of API and/or drug products. Second and third tier suppliers are out of scope

The section makes reference to the Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentrations (PNECs) targets developed by Alliance members.

When completing the survey, please refer to the AMRIA 2021 Survey Guidance document provided.

Section 4 Sub-section A: Assessing own sites and products against the criteria in the Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentration (PNEC) targets

	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
Applicable to	☑	☑		

Guidance:

In this sub-section, we will ask about the extent to which your own manufacturing sites have been assessed against the Alliance's Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentration (PNEC) targets. By your own antibiotic manufacturing sites, we mean sites under direct control or ownership of the company in which an antibiotic API and/or drug product (i.e. formulated products) is manufactured.

In the 2020 progress report survey you were provided with guidance in order to assess the extent to which your sites 'fully meet', 'partially meet' and 'do not meet' the Alliance's Common Antibiotic Manufacturing Framework and the list of PNEC targets, and were asked to submit the number of sites that 'fully meet', 'partially meet' and 'do not meet' the requirements. This year's survey follows a similar approach. However, this year, based on feedback obtained from sector consultations conducted as part of the process of designing the survey, we ask that you submit anonymised findings from the evaluation of your different sites. This will enable us to obtain a more nuanced understanding of diversity and variation in the performance of sites that a single company may own. We ask that you do not provide the name of the sites when answering this question but rather use 'Site 1, Site 2, Site 3...'. However, to ensure we obtain accurate data for analysis, please use the same number (e.g. Site 1) to provide answers for the same site. We have provided you with an Excel sheet with the different criteria found in the Alliance's Common Antibiotic Manufacturing Framework for manufacturing sites. We ask that you submit your answers related to evaluation from each of your own antibiotic manufacturing sites in this sheet. This sheet will be used by the research team to analyse the findings and will not be shared with the Alliance Secretariat. Please submit your forms to: AMRIA2021survey@randeurope.org

In addition, there are survey questions that allow you to submit an aggregate status of your sites (i.e. 'How many of your own manufacturing sites 'meet' the Alliance's Common Antibiotic Manufacturing Framework requirements'?). These are in the body of the survey below.

82. Does your company manufacture antibiotics at your own manufacturing sites? (Tick one of the following options)

- ☐ Yes
- ☐ No

Section 4 Sub-section A: Assessing own sites and products against the criteria in the Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentration (PNEC) targets (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		

83. As of 31st March 2021, how many of your own antibiotic manufacturing sites do you have? *

84. The Common Antibiotic Manufacturing Framework requires auditing of manufacturing sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As of 31st March 2021, does your company perform audits on meeting key requirements of the Common Antibiotic Manufacturing Framework for your own antibiotic manufacturing sites every 5 years? (Tick one of the following options) *

- ☐ Yes
- ☐ No, please briefly explain reason

85. The Common Antibiotic Manufacturing Framework requires auditing of manufacturing sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As of 31st March 2021, at a company level, which of the following best describes the extent to which your company meets the requirement to conduct audits of your own antibiotic manufacturing sites? (Tick one of the following options) Guidance: For information on the Pharmaceutical Supply Chain Initiative (PSCI) audit programme, please see the PSCI Audit Programme Guidance. Audits include internal review of site and external site tour to verify that operating conditions and practices are in place and are being appropriately followed. The question considers whether all requirements of 'Audits of Antibiotic Manufacturers' (as described in the Common Antibiotic Manufacturing Framework) are in place and whether your company follows PSCI audit best practice, and whether sites are pro-active on acting on audit findings. An audit tour verifies that operating conditions and practices are in place and are being followed as required. Meeting key requirements of 'Audits of Antibiotic Manufacturers' also requires that audits are performed of own sites at least every 5 years. *

- ☐ Our company has **all** requirements of 'Audits of Antibiotic Manufacturers' in place and follows Pharmaceutical Supply Chain Initiative (PSCI) audit best practice

- [ ] Our company has some requirements of 'Audits Antibiotic Manufacturer' in place and follows some elements of PSCI audit best practice
- [ ] Our company has no requirements of 'Audits Antibiotic Manufacturer' in place and does not follow elements of PSCI audit best practice

86. The Common Antibiotic Manufacturing Framework requires auditing of manufacturing sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As part of this program, companies are asked to conduct internal reviews of their own manufacturing sites to verify that operating conditions and practices are in place and appropriately followed. Which of the following best describes your company's internal review of your own antibiotic manufacturing sites? (Tick one of the following options) Guidance: As defined in the Common Antibiotic Manufacturing Framework, by internal review, we mean determining whether a site has in place i) compliance with regulatory requirements and permit conditions; (ii) risk assessment of antibiotic discharge and assessing these discharges against risk-based targets for discharge concentrations or overall load; (iii) maintenance plans (for critical equipment and environmental controls); iv) incident investigation logs; (v) supplier practices for evaluating their own supply chain; and (vi) waste and wastewater disposal records). If the review process considers all of the items listed in the guidance above, it is considered to be adequate. If the review is deficient in one or more of the items listed in the guidance above, it is considered to be inadequate. *

- [ ] We have adequate internal review of sites to verify that operating conditions and practices are in place and are being appropriately followed
- [ ] We have inadequate internal review of sites to verify that operating conditions and practices are in place and are being appropriately followed
- [ ] We do not have internal review of sites to verify that operating conditions and practices are in place and are being appropriately followed

87. The Common Antibiotic Manufacturing Framework requires auditing of manufacturing sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As part of this program, companies are asked to conduct external site tours of their own manufacturing sites to verify that operating conditions and practices are in place and appropriately followed. Which of the following best describes your company's external review of your own antibiotic manufacturing sites? (Tick one of the following options) Guidance: As defined in the Common Antibiotic Manufacturing Framework, external site tours includes assessment of discharge locations, pollution control devices, and receiving stream identification and observation. If the review process considers all of the items listed in the guidance above, it is considered to be adequate. If the review is deficient in one or more of the items listed in the guidance above, it is considered to be inadequate. *

- [ ] We have adequate external site tours to verify that operating conditions and practices are in place and are being appropriately followed

- [ ] We have inadequate external site tours to verify that operating conditions and practices are in place and are being appropriately followed
- [ ] We do not have external site tours to verify that operating conditions and practices are in place and are being appropriately followed

88. The Common Antibiotic Manufacturing Framework requires auditing of manufacturing sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As part of this program, companies are asked to have adequate mechanisms in place that ensure sites are able to proactively respond to audit findings. Which of the following best describes the mechanisms your company has in place to ensure that your own sites act pro-actively in response to audit findings? (Tick one of the following options) Guidance: If the review process considers all of the items listed in the guidance above, it is considered to be adequate. If the review is deficient in one or more of the items listed in the guidance above, it is considered to be inadequate. *****

- [ ] We have adequate mechanisms in place that ensure our own sites act pro-actively in response to audit findings
- [ ] We have inadequate mechanisms in place to ensure timely response to audit findings
- [ ] We have no mechanisms in place to ensure own sites act pro-actively in response to audit finding

89. As of 31st March 2021 how many of your own antibiotic manufacturing sites have been assessed against the criteria in the Common Antibiotic Manufacturing Framework? *

90. As of 31st March 2021, among your own antibiotic manufacturing sites that have been assessed against the criteria in the Common Antibiotic Manufacturing Framework, please provide the following: Guidance: You must input a number for each line below. Please input 0 if not applicable. For a site to be considered to 'fully meet' the Common Antibiotic Manufacturing Framework requirements, all criteria for the site in the Excel sheet for 'own manufacturing sites' must be answered with the drop-down option 'yes'. For a site to be considered to 'partially meet' the Common Antibiotic Manufacturing Framework requirements, at least one criterion for the site in the Excel sheet for 'own manufacturing sites' must be answered with the drop-down option 'partially' but no criteria should be answered with the drop-down option 'no'. For a site to be considered to 'not meet' the Common Antibiotic Manufacturing Framework requirements, at least one criterion for the site in the Excel sheet for 'own manufacturing sites' must be answered with the drop-down option 'no' or 'do not know'. In order to assess the extent to which your sites meet the requirements of the Common Antibiotic Manufacturing Framework we encourage you to submit your evaluation in the Excel sheet provided, as this will automatically capture the number of sites that 'fully meet', 'partially meet' or 'do not meet' and provide the evidence source for the questions asking for aggregate data in the survey. The sum of your answer should equal the number of own antibiotic sites provided at the start of the section. *

How many sites **fully meet** the Common Antibiotic Manufacturing Framework requirements? *

How many **partially meet** the Common Antibiotic Manufacturing Framework requirements? *

How many **do not meet** the Common Antibiotic Manufacturing Framework requirements? *

91. How many of your own antibiotic manufacturing sites that have been assessed but do not currently meet the Common Antibiotic Manufacturing Framework requirements, do you anticipate meeting the requirements in the following time frames, using 31 March 2021 as a starting point: Guidance: You must input an answer for each time frame below. If all your sites currently fully meet or partially meet the requirements, please input N/A in each text box. If you do not know or cannot anticipate this, please type 'we cannot anticipate this/do not know'. Please only count each site once. For example, if you have 8 sites that do not currently meet the requirements, you might put 5 will meet requirements in 0-1 years, a further 2 more will meet requirements in 2-3 years, and the final site will meet requirements in 4-5 years. The sum of your answer should equal the number of own antibiotic sites that do not meet the Common Antibiotic Manufacturing Framework requirements provided in the previous question. *****

0-1 years *

2-3 years *

4-5 years *

None of the above (please specify reason)

92. As of 31st March 2021 how many of your own antibiotic manufacturing sites have not been assessed against the criteria in the Common Antibiotic Manufacturing Framework? *****

93. How many of your own antibiotic manufacturing sites that have not been assessed against the Common Antibiotic Manufacturing Framework do you anticipate being assessed in the following time frames, using 31 March 2021 as a starting point: Guidance: You must input an answer for each time frame below. Please only count each site once. For example, if you have 8 sites that have not been assessed, you might put 5 will be assessed in 0-1 years, a further 2 more will be assessed in 2-3 years, and the final site will be assessed in more than 3 years' time. The sum of your answer should equal the number of own antibiotic sites that have not been assessed as reported in the previous question *****

0-1 years *

2-3 years *

>3 years *

If more than 3 years, please specify reason

94. [OPTIONAL] What actions did your company take in the time period between 1st July 2019 and 31st March 2021 to ensure that your own antibiotic manufacturing sites meet the Common Antibiotic Manufacturing Framework requirements? (max 1000 words) Guidance: Please note that we do not plan to report on this information by company – rather the narrative in the report will provide a snapshot of the diversity of types of actions companies take to demonstrate the activities and contributions of a sector, in an anonymised manner. However, please be mindful of not disclosing commercially sensitive information that you would not want reported even in an anonymised manner.

95. As of 31st March 2021, how many antibiotic products are manufactured at your own sites? Note: At own sites the number of products is the number of different APIs made and/or the number of different APIs used (to make a Drug Product) at a given site. If a site makes both API and drug products, count the number of different APIs made and used. If an API is made and the same API is used to make a drug product at the same site, count as 2 products (because a separate assessment of PNEC adherence will be performed for the API manufacture and the drug product manufacture). If an API is used to make a drug product at 3 different own manufacturing sites then this is counted as 3 products (again because 3 different assessments of PNEC adherence will be performed, one per site) *****

96. How many antibiotic products manufactured at your own sites have been assessed against PNEC targets? Guidance: The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. *****

97. As of 31st March 2021, of the antibiotic products manufactured at your own site that have been assessed against PNEC targets, how many meet the PNEC targets? Guidance: The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. *

98. Based on the number of antibiotic products manufactured at your own sites that have been assessed against PNEC targets that do not currently meet PNEC targets, how many do you anticipate meeting the PNEC targets in the following time frames, using 31 March 2021 as a starting point: Guidance: The definition of a product is: The number of different APIs made and/or the number of different APIs used (to make a Drug Product) at a given site. If a site makes both API and drug products, count the number of different APIs made and used. If an API is made and the same API is used to make a drug product at the same site, count as 2 products (because a separate assessment of PNEC adherence will be performed for the API manufacture and the drug product manufacture). If an API is used to make a drug product at 3 different own manufacturing sites then this is counted as 3 products (again because 3 different assessments of PNEC adherence will be performed, one per site. The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. *

0-1 years *

2-3 years *

4-5 years *

None of the above (please specify reason)

99. As of 31st March 2021 how many antibiotic products manufactured at your own sites have not been assessed against PNEC targets? *****

100. How many antibiotic products manufactured at your own sites that have not been assessed against PNEC targets do you anticipate being assessed in the following time frames, using 31 March 2021 as a starting point: Guidance: You must input an answer for each time frame below. The definition of a product is: The number of different APIs made and/or the number of different APIs used (to make a Drug Product) at a given site. If a site makes both API and drug products, count the number of different APIs made and used. If an API is made and the same API is used to make a drug product at the same site, count as 2 products (because a separate assessment of PNEC adherence will be performed for the API manufacture and the drug product manufacture). If an API is used to make a drug product at 3 different own manufacturing sites then this is counted as 3 products (again because 3 different assessments of PNEC adherence will be performed, one per site *****

0-1 years *

2-3 years *

>3 years *

If more than 3 years, please specify reason

101. [OPTIONAL] What actions did your company take in the time period between 1st July 2019 and 31st March 2021 to ensure that your own antibiotic manufacturing sites' products meet the PNEC targets? (max 1000 words) Guidance: The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. Please note that we do not plan to report on this information by company – rather the narrative in the report will provide a snapshot of the diversity of types of actions companies take to demonstrate the activities and contributions of a sector, in an anonymised manner. However, please be mindful of not disclosing commercially sensitive information that you would not want reported even in an anonymised manner.

Section 4 Sub-section B: Conveying expectations of the Common Antibiotic Manufacturing Framework to direct suppliers

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		

Guidance:

In this sub-section, we will ask about any efforts your company has undertaken to convey the expectations of the Common Antibiotic Manufacturing Framework to your direct suppliers.

By direct antibiotic manufacturing suppliers, we mean sites outside of the direct control or ownership of the company that supply an Alliance member company with an antibiotic API and/or drug product (i.e. formulated products).

The scope of the survey is on direct suppliers of API and/or drug products. Second and third tier suppliers are out of scope.

102. Does your company manufacture antibiotics at direct supplier sites? (Tick one of the following options) *

- ☐ Yes
- ☐ No

Section 4 Sub-section B: Conveying expectations of the Common Antibiotic Manufacturing Framework to direct suppliers (cont.)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑		

103. As of 31st March 2021, how many direct antibiotic manufacturing suppliers do you have? *****

104. As of 31st March 2021, how many of your company's direct antibiotic manufacturing suppliers have had the expectations of the Common Antibiotic Manufacturing Framework conveyed to them by your company? *

105. [OPTIONAL] How has your company conveyed the expectations of Common Antibiotic Manufacturing Framework to your direct antibiotic manufacturing suppliers? (max 500 words)

Section 4 Sub-section C: Assessing direct supplier sites and products against the criteria in the Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentration targets

	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
Applicable to	☑	☑		

Guidance:

In this sub-section, we will ask about the extent to which your direct supplier manufacturing sites have been assessed against the Alliance's Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentration (PNEC) targets. By direct antibiotic manufacturing suppliers, we mean sites outside of the direct control or ownership of the company that supply an Alliance member company with an antibiotic API and/or drug product (i.e. formulated products). The scope of the survey is on direct suppliers of API and/or drug products. Second and third tier suppliers are out of scope.

In the 2020 progress report survey you were provided with guidance in order to assess the extent to which your direct antibiotic manufacturing supplier sites 'fully meet', 'partially meet' and 'do not meet' the Alliance's Common Antibiotic Manufacturing Framework and the list of PNEC targets, and were asked to submit the number of direct supplier sites that 'fully meet', 'partially meet' and 'do not meet' the requirements. This year's survey follows a similar approach. However, this year, based on feedback obtained from sector consultations conducted as part of the process of designing the survey, we ask that you submit anonymised findings from the evaluation of your different direct supplier sites. This will enable us to obtain a more nuanced understanding of diversity and variation in the performance of sites that a single company may engage with. We ask that you do not provide the name of the direct supplier sites when answering supplier-specific questions but rather use 'Supplier 1, Supplier 2, Supplier 3...'. However, to ensure we obtain accurate data for analysis, please use the same number (e.g. Supplier 1) to provide answers for the same direct supplier site. We have provided you with an Excel sheet with the different criteria found in the Alliance's Common Antibiotic Manufacturing Framework for direct supplier sites. We ask that you submit your answers related to evaluations from each of your direct supplier antibiotic manufacturing sites in this sheet. This sheet will be used by the research team to analyse the evaluations and will not be shared with the Alliance Secretariat. Please submit your forms to: AMRIA2021survey@randeurope.org

In addition, there are survey questions that allow you to submit an aggregate status of your direct supplier sites (i.e. 'How many of your direct supplier manufacturing sites 'meet' the Alliance's Common Antibiotic Manufacturing Framework requirements'?).

106. The Common Antibiotic Manufacturing Framework requires auditing of manufacturing sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As of 31st March 2021, does your company perform audits on meeting key requirements of the Common Antibiotic Manufacturing Framework for your direct antibiotic manufacturing suppliers every 5 years? (Tick one of the following options) *****

- [ ] Yes
- [ ] No, please briefly explain reason

107. The Common Antibiotic Manufacturing Framework requires auditing of direct manufacturing supplier sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As part of this program, companies are asked to conduct external site tours of their direct supplier sites to verify that operating conditions and practices are in place and appropriately followed. Which of the following best describes your company's external review of your direct antibiotic manufacturing suppliers? (Tick one of the following options) Guidance: As defined in the Common Antibiotic Manufacturing Framework, external site tours includes assessment of discharge locations, pollution control devices, and receiving stream identification and observation. If the review process considers all of the items listed in the guidance above, it is considered to be adequate. If the review is deficient in one or more of the items listed in the guidance above, it is considered to be inadequate. *****

- [ ] We have **adequate** external site tours to verify that operating conditions and practices are in place and are being appropriately followed at our direct supplier sites.
- [ ] We have **inadequate** external site tours to verify that operating conditions and practices are in place and are being appropriately followed
- [ ] We **do not have** external site tours to verify that operating conditions and practices are in place and are being appropriately followed

108. The Common Antibiotic Manufacturing Framework requires auditing of direct supplier sites at least every 5 years to ensure that antibiotics manufacturing facilities minimize their environmental impact. As part of this program, companies are asked to have adequate mechanisms in place that ensure sites are able to proactively respond to audit findings. Which of the following best describes the mechanisms your company has in place to ensure that your direct supplier sites act pro-actively in response to audit findings? (Tick one of the following options) Guidance: If the review process considers all of the items listed in the guidance above, it is considered to be adequate. If the review is deficient in one or more of the items listed in the guidance above, it is considered to be inadequate. *****

- [ ] We have **adequate** mechanisms in place that ensure our direct supplier sites act pro-actively in response to audit findings
- [ ] We have **inadequate** mechanisms in place to ensure our direct suppliers have a timely response to audit findings

☐ We have no mechanisms in place to ensure that our direct supplier sites act pro-actively in response to audit finding

109. As of 31st March 2021 how many of your direct antibiotic manufacturing suppliers do you know have been assessed against the criteria in the Common Antibiotic Manufacturing Framework? If you do not know, please type 'Unknown' in the box. *****

110. As of 31st March 2021, among your direct antibiotic manufacturing suppliers that have been assessed against the criteria in the Common Antibiotic Manufacturing Framework, please provide the following: Guidance: You must input a number for each line below. If not applicable, please input 0. For a direct supplier site to be considered to 'fully meet' the Common Antibiotic Manufacturing Framework requirements, all criteria for the site in the Excel sheet for 'direct supplier manufacturing sites' must be answered with the drop-down option 'yes'. For a direct supplier site to be considered to 'partially meet' the Common Antibiotic Manufacturing Framework requirements, at least one criterion for the site in the Excel sheet for 'direct supplier manufacturing sites' must be answered with the drop-down option 'partially' but no criteria should be answered with the drop-down option 'no'. For a direct supplier site to be considered to 'not meet' the Common Antibiotic Manufacturing Framework requirements, at least one criterion for the site in the Excel sheet for 'direct supplier manufacturing sites' must be answered with the drop-down option 'no' or 'do not know'. In order to assess the extent to which your sites meet the requirements of the Common Antibiotic Manufacturing Framework we encourage you to submit your audit findings in the Excel sheet provided, as this will automatically capture the number of sites that 'fully meet', 'partially meet' or 'do not meet' and provide the evidence source for the questions asking for aggregate data in the survey. The sum of your answer should equal the number of own antibiotic sites provided at the start of the section. *****

How many direct supplier sites fully meet the Common Antibiotic Manufacturing Framework requirements? *

How many direct supplier sites partially meet the Common Antibiotic Manufacturing Framework requirements? *

How many direct supplier sites do not meet the Common Antibiotic Manufacturing Framework requirements? *

111. Based on the number of direct supplier antibiotic manufacturing sites that do not currently meet do not currently meet the requirements of the Common Antibiotic Manufacturing Framework as indicated above, how many do you anticipate meeting the requirements in the following time frames, using 31 March 2021 as a starting point: Guidance: You must input an answer for each time frame below. If all your direct supplier sites currently fully meet or partially meet the requirements, please input N/A in each text box. If you do not know or cannot anticipate this, please type 'we cannot anticipate this/do not know'. Please only count

each site once. For example, if you have 8 direct supplier sites that do not currently meet the requirements, you might put 5 will meet requirements in 0-1 years, a further 2 more will meet requirements in 2-3 years, and the final site will meet requirements in 4-5 years. *****

0-1 years *

2-3 years *

4-5 years *

None of the above (please specify reason)

112. As of 31st March 2021 how many of your direct antibiotic manufacturing supplier sites do you know have not been assessed against the criteria in the Common Antibiotic Manufacturing Framework? If you do not know, please type 'Unknown' in the box. *****

113. How many of your direct antibiotic manufacturing supplier sites that have not been assessed against the Common Antibiotic Manufacturing Framework do you anticipate being assessed in the following time frames, using 31 March 2021 as a starting point: Guidance: You must input an answer for each time frame below. Please only count each site once. For example, if you have 8 sites that have not been assessed, you might put 5 will be assessed in 0-1 years, a further 2 more will be assessed in 2-3 years, and the final site will be assessed in more than 3 years' time. The sum of your answer should equal the number of own antibiotic sites that have not been assessed as reported in the previous question *****

0-1 years *

2-3 years *

>3 years *

If more than 3 years, please specify reason

114. As of 31st March 2021, how many of your antibiotic products are manufactured at your direct supplier sites? Guidance: At direct supplier sites the number of products is the number

of different APIs made and/or the number of different APIs used (to make a Drug Product) at a given site. If a site makes both API and drug products, count the number of different APIs made and used. If an API is made and the same API is used to make a drug product at the same site, count as 2 products (because a separate assessment of PNEC adherence will be performed for the API manufacture and the drug product manufacture). If an API is used to make a drug product at 3 different own manufacturing sites then this is counted as 3 products (again because 3 different assessments of PNEC adherence will be performed, one per site *****

115. How many antibiotic products manufactured at your direct supplier sites have been assessed against PNEC targets? Guidance: The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. *****

116. How many of your antibiotic products manufactured at your direct supplier sites meet the PNEC targets? Guidance: The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. *****

117. Based on the number of your antibiotic products manufactured at your direct supplier sites that do not currently meet PNEC targets, how many do you anticipate meeting the PNEC targets in the following time frames, using 31 March 2021 as a starting point: Guidance: You must input an answer for each time frame below. If you do not know or cannot anticipate this, please type 'we cannot anticipate this/do not know'. The definition of a product is: The number of different APIs made and/or the number of different APIs used (to make a Drug Product) at a given site. If a site makes both API and drug products, count the number of different APIs made and used. If an API is made and the same API is used to make a drug product at the same site, count as 2 products (because a separate assessment of PNEC adherence will be performed for the API manufacture and the drug product manufacture). If an API is used to make a drug product at 3 different own manufacturing sites then this is counted as 3 products (again because 3 different assessments of PNEC adherence will be performed, one per site The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting

ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. *****

0-1 years *

2-3 years *

4-5 years *

None of the above (please specify reason)

118. As of 31st March 2021 how many antibiotic products manufactured at your direct supplier sites have not been assessed against PNEC targets? *****

119. How many antibiotic products manufactured at your direct supplier sites that have not been assessed against PNEC targets do you anticipate being assessed in the following time frames, using 31 March 2021 as a starting point: Guidance: The definition of a product is: The number of different APIs made and/or the number of different APIs used (to make a Drug Product) at a given site. If a site makes both API and drug products, count the number of different APIs made and used. If an API is made and the same API is used to make a drug product at the same site, count as 2 products (because a separate assessment of PNEC adherence will be performed for the API manufacture and the drug product manufacture). If an API is used to make a drug product at 3 different own manufacturing sites then this is counted as 3 products (again because 3 different assessments of PNEC adherence will be performed, one per site *****

0-1 years *

2-3 years *

>3 years *

If more than 3 years, please specify reason

120. [OPTIONAL] What actions did your company take in the time period between 1st July 2019 and 31st March 2021 to ensure that your direct antibiotic manufacturing suppliers meet the PNEC targets? (max 1000 words) Guidance: The PNEC targets are risk-based values for use in risk assessment of discharge concentrations in the receiving water body for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimizing selective pressure on bacteria in the receiving water body to mutate (and thus minimize potential risk of development of resistance) incorporating assessment factors consistent with standard environmental risk methodologies. A table with the PNEC targets can be found here. Please note that we do not plan to report on this information by company – rather the narrative in the report will provide a snapshot of the diversity of types of actions companies take to demonstrate the activities and contributions of a sector, in an anonymised manner. However, please be mindful of not disclosing commercially sensitive information that you would not want reported even in an anonymised manner.

Case vignette (Optional)

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	☑	☑	☑	☑

121. Throughout this survey we have asked you to provide examples of various activities to help us tell a richer story of the contributions of your sector. In addition, in this section, you have the opportunity to submit one key flagship story of progress by your company in tackling AMR, which we may feature as a somewhat longer standalone case-vignette in the progress report. This is anticipated to be approximately one to two pages in length. It could speak to any aspect of your contributions in the time period between 1st July 2020 and 31st March 2021 – be it R&D, access, appropriate use or manufacturing, or it can span more than one dimension of your contributions to the fight against AMR. We are looking for case vignettes of new activities – i.e. we do not wish to repeat information which was already profiled in prior progress reports. We

are looking to feature case vignettes of good practice that also support learning about what works in tackling AMR, and we will seek a mix of examples to profile across different company types and geographies. The submitted case studies will be reviewed in consultation with the Alliance Secretariat and sector champions, to make final decisions as to which cases to profile, considering degree of impact, diversity of activity, diversity of company types/sectors represented and diversity of geographies. If your case vignette is selected for inclusion in the report, we will use the information you provided and contact you to confirm any suggested edits related to keeping in line with the tone of the overall report and to ensure that you have the correct permissions in place for us to include the case vignette in the final report. Please complete the following information in the text box below and use the following subheadings, in the text box provided 1) Company name 2) Geographical location (either of headquarters or of specific unit as relevant to case vignette- please make clear which it is) 3) Suggested title of case vignette (e.g. this may be related to a programme or initiative or specific type of activity) 4) Description of the AMR relevant health challenge being tackled 5) Aims of the initiative/activities you are describing and why you pursued it 6) Whether it relates to any specific AMR-relevant pathogens, products and/or technologies 7) How much funding was invested (if applicable and not commercially sensitive) 8) Timeframe of the activity 9) How you implemented your initiative/programme/activities. To cover: a. What were the core parts of your effort- a brief description of how it unfolded) b. Did you collaborate with any organisations externally (to the extent not commercially-sensitive and confidential) 10) What were the key enablers of your effort? I.E. What factors helped you out along the way? 11) What were the key barriers and challenges you experienced in your effort? 12) What outcomes and impacts were achieved as of 31st March 2021, as a result of your efforts? 13) Are any additional outcomes and impacts anticipated in the future, if any? In providing your case example, please be mindful not to disclose commercially sensitive information as your case vignette may be publically profiled in the report. Please keep your total answer to 1000 words maximum.

Annex B. Additional information on research and science

B.1. INVESTMENT IN RESEARCH AND SCIENCE

Across the Alliance, 25% (n=13) of companies reported investing over US$20 million in R&D for AMR-relevant products and/or technologies in FY2019. A further 6% (n=3) of companies reported they invested US$16—20 million, 8% (n=4) of companies invested between US$11–15 million, 13% (n=7) of companies invested between US$6–10 million, 21% (n=11) of companies invested between US$1–5 million and 19% (n=10) of companies invested less than US$1 million (Figure 1). In FY2020, 23% (n=12) of companies reported investing over US$20 million in R&D for AMR-relevant products and/or technologies, with a further 11% (n=6) of companies reported they invested between US$16–20 million, 4% (n=2) of companies invested between US$11–15 million, 13% (n=7) of companies invested between US$6–10 million, 26% (n=14) of companies invested between US$1–5 million and 13% (n=7) of companies invested less than US$1 million (Figure 2). Across both FY2019 and FY2020, 9% of respondents reported that they did not invest in R&D for AMR-relevant products and/or technologies. However, this option was only presented to companies in the generics sector as they are not expected to be involved in R&D.

Unsurprisingly, most investments over US$20 million in FY2019 and FY2020 came from larger R&D pharmaceutical companies (n=7, 58% of respondent R&D pharmaceutical companies). However, some diagnostics companies (n=1, 20% of respondent diagnostics companies), biotech/SMEs (n=4, 15% of respondent biotech/SMEs in FY2019, and n=3, 11% respondent biotech/SMEs in FY2020) and generics companies (n=1, 11% respondent generics companies in FY2019 and FY2020) also reported investments over US$20 million. As expected, some generics companies did not invest in AMR-relevant R&D (n=5, 56%). Including generics companies in investment-related questions in the future, as in this round, would continue to provide a more rounded vision of overall Alliance investment in AMR-relevant R&D as this sector also contributes.

Over half the companies in the R&D pharmaceutical sector (n=7, 58% of respondent R&D pharmaceutical companies) spent over US$20 million in FY2019 and FY2020 (Figure 1 and Figure 2), with a range of combined investment between US$1.14–1.18 billion in FY2019 and US$1.05–1.1 billion in FY2020. However, it is worth keeping in mind that two large companies did not provide an actual value for their investment, which is above US$20 million, given they provided this range as their answer. In addition, one company specifically stated that they excluded their investment in COVID-19 related work, which may impact their overall investment in AMR-relevant R&D.

The diagnostics sector had a combined investment between US$388–400 million in FY2019 and US$448–461 million in FY2020 across the sector survey respondents. Biotech/SMEs invested between US$249–329 million in FY2019 and US$268–338 million in FY2020 across biotech/SME-sector survey respondents. Although over half of generics companies (n=5, 56% of respondent generics companies) reported no investments in FY2019 or FY2020, the sector reported a combined investment of between US$27–36 million in FY2019 and US$27–36 million in FY2020.

B.2. GLOBAL AMR R&D HUB INCENTIVES

TABLE B2-1. INCENTIVES FOR ANTIBACTERIAL R&D (ADAPTED FROM THE GLOBAL AMR R&D HUB)

Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
Discovery and translational research	Supporting early-stage R&D	Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)	Multiple	CARB-X is a global non-profit partnership supporting early-stage antibacterial product development through mechanisms such as non-dilutive funding, expert support, and cross-project initiatives to accelerate candidates towards clinical development and regulatory approval. CARB-X's current portfolio of active 58 projects (September 2021) is the world's largest early development pipeline of antibacterial projects and currently comprises 35 therapeutics, 12 preventatives and 11 rapid diagnostics.
		Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)	Multiple	JPIAMR is a global collaborative organisation and platform supporting the AMR research community through funding coordination and network building & support. JPIAMR's networking calls coordinate national research investments to jointly fund transnational research within six priority areas of its Strategic Research and Innovation Agenda (SRIA), one of which is therapeutics. JPIAMR also provides financial support to research networks & virtual research institutes. In Oct 2020, JPIAMR released its AMR Research Infrastructure Dashboards, which aims to provide an accessible overview of global collections of biological materials, databases and research infrastructure services.
		Replenishing and Enabling the Pipeline for Anti-Infective Resistance (REPAIR) Impact Fund	Denmark	The REPAIR Impact Fund invests in start-ups, early-stage companies and spin-outs to support programmes addressing AMR through new therapeutics. The Fund prioritises compounds targeting the highest pathogen priorities and first-in-class therapies, from the early stage of drug development to the early stages of clinical development (Phase 1). Between 2016 and March 2021, the REPAIR Fund invested in nine different companies globally, with a total value of around US$65 million.

Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
Clinical research: Phase I, Phase II, Phase III	Enhancing clinical trial conduct	European Clinical Research Alliance on Infectious Diseases (ECRAID)	EU	Launched in March 2021, ECRAID is a pan-European clinical research network. Supported by the European Commission, ECRAID comprises six perpetual clinical studies already encompassing more than 2,000 sites in more than 40 countries. ECRAID aims to become a self-sustaining non-profit organisation conducting clinical research for public and private sponsors through adaptive platform trials. The network has already been utilised in response to COVID-19.
		Combatting Bacterial Resistance in Europe (COMBACTE)	EU	The EU's COMBACTE-NET, a clinical trial and laboratory network comprising 994 sites and 763 laboratories, aims to improve the flow of new antibacterial drugs. The network comprises around 15 trials within 3 main sub-networks: CLIN-NET (patient recruitment), LAB-NET and STAT-NET (optimising the design of PII-PIII trials). The latter has a workstream focused on innovative trial design for antibiotic clinical development. In early 2021, the network's CLIN & LAB-NET components were extended for a further two years to 2023.
		Antibacterial Resistance Leadership Group (ARLG)	US	ARLG is a network comprising more than 50 leading experts working together to address antibacterial resistance and improve patient care. ARLG contributes to innovative clinical trial design, access to clinically well-characterised bacteria, and opportunities for early-stage investigators. The group has established collaborations in over 19 countries, including more than 50 clinical research studies involving more than 20,000 patients and 130 sites.
		Clinical Trials Transformation Initiative (CTTI)	US	CTTi drives increased quality and efficiency of clinical trials through cross-system collaboration. CTTi's Antibiotic Drug Development (ABDD) programme focuses on hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP), paediatrics, and unmet needs. In 2021, CTTi announced its 'transforming trials 2030' vision, leveraging COVID-19 learnings for the future of clinical trials.

Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
	Supporting late-stage R&D	Global Antibiotic Research and Development Partnership (GARDP)	Multiple	GARDP is a not-for-profit organisation mobilising cross-sectoral partners and resources to support the development of treatments targeting gaps in AMR product development. GARDP currently has four core programmes, covering serious bacterial infections, children's antibiotics, sexually transmitted infections and discovery and exploratory activities to identify new antibiotics for new and under-explored targets. GARDP's goal is to deliver five new treatments by 2025.
		AMR Action Fund	Multiple	Established in July 2020, the AMR Action Fund expects to invest over US$1 billion over ten years to support the development of 2–4 antibiotics through phase II-III clinical trials to market by 2030. An independent Scientific Advisory Board will develop recommendations for assets to be considered for investment, focusing on innovative antibacterials targeting WHO or CDC priority pathogens. The AMR Action Fund's first investments are anticipated to be announced in 2021.
		Biomedical Advanced Research and Development Authority (BARDA) Broad Spectrum Antimicrobials (BSA) Programme	US	The US BARDA's BSA programme provides non-dilutive funding to support the development of novel antibacterial and antiviral drugs to treat or prevent diseases caused by biological threats. Industry partners of BARDA can receive funding and expert technical advice to support clinical studies (Phase 1–3), manufacturing and regulatory activities.
		InnovFin Infectious Diseases Finance Facility (IDFF)	EU	The European Investment Bank´s IDFF provides a range of financial products (between EUR 7.5 million and EUR 75 million) to support the development of innovative vaccines, drugs, medical and diagnostic devices or novel research infrastructures for combating infectious diseases.

Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
1st national filing	Streamlining regulatory requirements	European Medicines Agency (EMA) and US Food and Drug Administration (FDA), Parallel Scientific Advice (PSA)	Multiple	EMA and FDA PSA procedures are voluntary and typically occur at the request of a sponsor requiring further scientific input from both agencies. The procedures are useful for important medicinal products, including products being developed for indications where development guidelines do not exist or products for which EMA and FDA's guidelines differ significantly.
		European Medicines Agency (EMA), US Food and Drug Administration (FDA), Japanese Pharmaceuticals and Medical Devices Agency (PMDA) Tripartite Platform	Multiple	Since 2016, the medicine regulators the of EU, US and Japan have held regular tripartite meetings to consider alignment opportunities and overcome challenges relating to differences between regulatory regimes.
		EMA: European Medicines Agency	EU	This entry aims to capture EMA´s guidance with respect to the development of antibacterial agents. Further detail is available on the EMA website (https://www.ema.europa.eu/en).
		FDA: Food & Drug Administration	US	This entry aims to capture FDA´s guidance with respect to the development of antibacterial agents. Further detail is available on the FDA website (https://www.fda.gov/).
		WHO Prequalification of Essential Medicines and Health Products (PQ) Programme	Multiple	Established in 2001, WHO´s PQ Programme facilitates access to medicines by performing assessments of the quality, safety and efficacy/performance of products to accepted international regulatory standards. The PQ programme facilitates the uptake of quality new medicines within national systems, particularly in countries with limited regulatory capacities.

Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
Global filings and label expansion	Earlier and broader uptake	Infectious Diseases Society of America (IDSA) Difficult-to-Treat Infections Guidance Series	US	The IDSA's Difficult-to-Treat series provides expert guidance for clinicians on treating resistant infections. The guidance documents are more restricted in scope than typical comprehensive clinical management guidelines but can be produced and subsequently updated more rapidly than regular guidance. The first guidance, published in September 2020, focuses on infections caused by three groups of AMR Gram-negative bacteria (ESBL-E, CRE, DTR-Pseudomonas) that pose particular therapeutic challenges and that the CDC has classified as urgent or serious threats.
		Biomedical Advanced Research and Development Authority (BARDA) Strategic Reserve Fund (SRF) and Strategic National Stockpile (SNS)	US	Under the 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), the US Government Project BioShield's SRF was reauthorised together with ten-year funding for product development. BARDA has the procurement authority for Project BioShield acquisitions utilising the SRF. In exceptional circumstances, BARDA may also utilise the Strategic National Stockpile of medical supplies.
Pricing & reimbursement	Enhancing relative market attractiveness	UK: Value-Based Subscription Model Project	UK	The UK Government's Value-Based Subscription Model (VBSM) pilot will use an innovative value assessment to determine a fixed annual fee payment to companies (max. ten million GBP). The pilot will employ a subscription-based approach where contract values are delinked from the volumes used, focusing on meeting UK demand over a period of up to ten years.
		Sweden: Exceptional Procurement Pilot	Sweden	Under this Swedish Government pilot scheme, companies able to guarantee a rapid and timely supply of newly approved antibiotics with particular medical value can receive a guaranteed minimum yearly income.

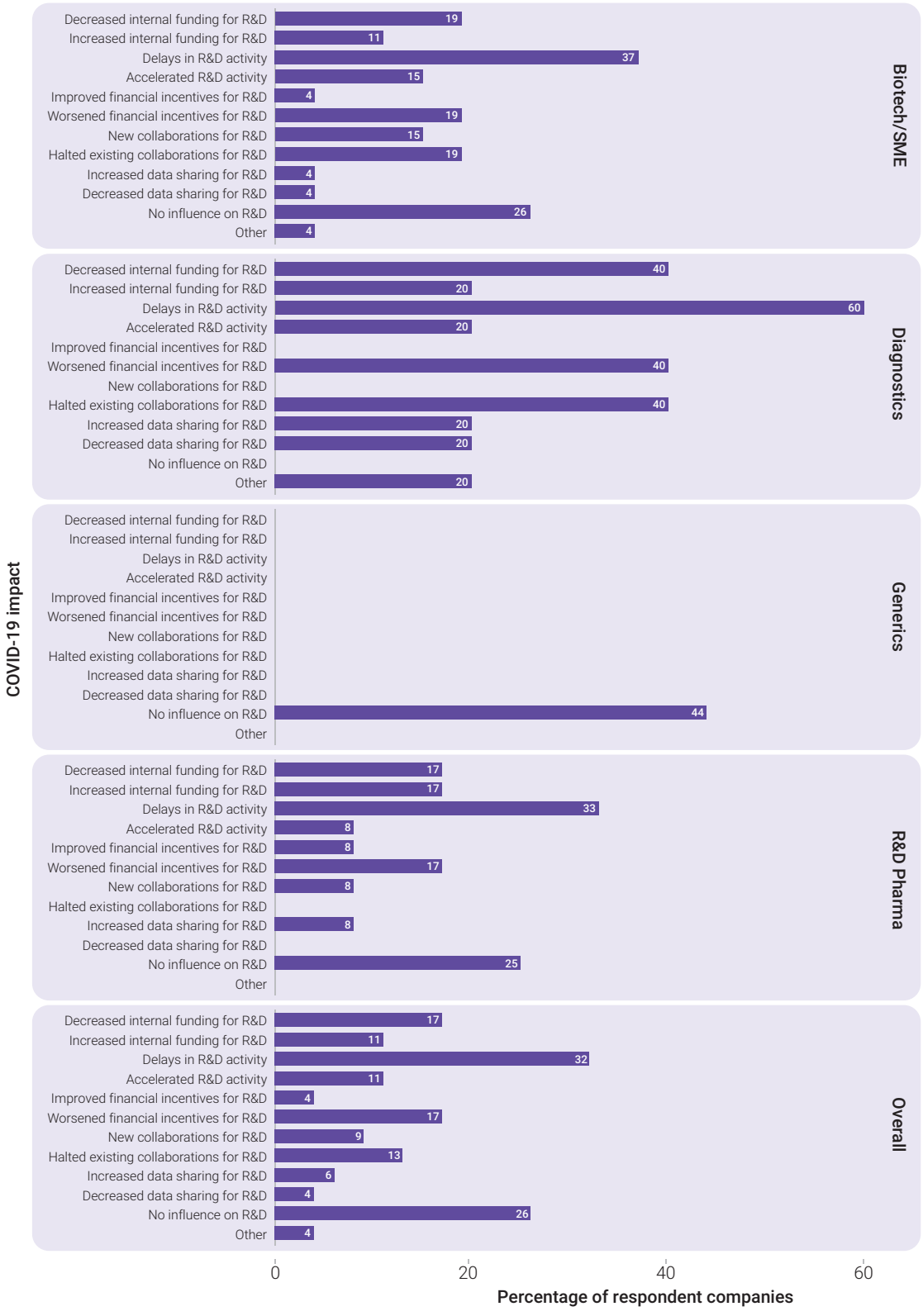
Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
		Germany: Additional Benefits Package (GKV-FWG)	Denmark	As a result of the creation of a 'reserve antibiotic' designation within the German Statutory Health Insurance system in April 2020, an antibiotic proven to be 'efficient against resistance' and with limited alternative therapy options is considered to have 'added benefit'. This, in turn, feeds into reimbursement negotiations between purchasers and companies. Antibiotics designated as 'reserve antibiotics' will be subject to product-specific stewardship provisions.
		US: Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act Subscription Model	US	The PASTEUR Act, reintroduced to the US Congress in June 2021, seeks to establish a subscription model (volume-delinked purchase contracts) for critical need antimicrobials used within the US Centers for Medicare & Medicaid Services (CMS). Under the Bill, individual subscription contracts would contain provisions for product availability, appropriate use and post-market studies and be valued between US$750 million and US$3 billion over ten years.
Distributing	Expediting sustainable global patient access	World Health Organization (WHO) Access, Watch and Reserve (AWaRe) Classification	Multiple	WHO's AWaRe classification divides 180 antibiotics into three stewardship groups, with 48 classified as 'Access', 110 as 'Watch' and 22 as 'Reserve'. The classification serves as a tool to facilitate antibiotic stewardship at the local, national and global levels. The AWaRe database also lists those antibiotics whose use is not recommended by WHO. WHO has a country-level target of at least 60% of all consumed antibiotics being from the 'Access' group by 2023.
		WHO Essential Medicines List (EML)	Switzerland	WHO's EML serves as a model for the development of national and institutional essential-medicine lists. The EML is revised every two years. The most recent (2019) version of the list covers 460 medicines and is used by over 150 countries. In 2020, WHO released a digital version with improved functionality and searching capabilities.

Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
Marketing	Priority signalling & orientation	The Pew Charitable Trusts: Pipeline Reviews	USA	The Pew Charitable Trusts' AMR team regularly reviews the clinical antibiotic pipelines for both small molecule compounds and non-traditional agents. Updates to the reviews are based on publicly available information and most recently published in March 2021. The small-molecule pipeline includes products that act systemically, contain at least one component not approved previously, and have the potential to treat serious or life-threatening infections. The pipeline for non-traditional products includes those intending to treat systemic bacterial infections in the clinical setting.
		WHO Priority Pathogen List (PPL)	Multiple	WHO's PPL is a catalogue of 12 families of bacteria prioritised into three groups (critical, high and medium priority) according to the urgency of the threat they pose to human health. The PPL aims to guide the prioritisation of incentives and funding, help align R&D priorities with public health needs and support global coordination in the fight against antibiotic-resistant bacteria.
		Centers for Disease Control and Prevention (CDC) Biggest Threats list	US	Presented in its Antibiotic Resistance Threats Report, the CDC's Biggest Threats report lists antibiotic-resistant bacteria and fungi in three categories –'urgent', 'serious', and 'concerning' – based on the level of concern to human health. The CDC report also includes a Watch List for threats for which resistance has not yet spread widely but where resistance could become common in the absence of aggressive action.
		WHO Target Product Profiles (TPPs)	Multiple	WHO's TPPs provide companies and other stakeholders in product development with a list of specific characteristics for a future treatment to optimally meet an unmet public health need. WHO may engage in the development of TPPs in response to priority unmet medical needs, emergency or epidemic scenarios, or where there is a commitment to accelerate product development. WHO has published TPPs relevant to AMR addressing enteric fever, gonorrhoea, neonatal sepsis and urinary tract infections.

Stage of research	Actions	Initiatives	Countries of focus	Description of initiative
		WHO Development Pipeline Reviews	Multiple	WHO conducts frequent reviews of clinical and preclinical antibacterial pipelines. Typically published in the first quarter of each year, these reviews are complemented by a biannual analytical report. Through these reviews, WHO aims to provide oversight of global development efforts as well as a baseline for progress. In addition to the clinical and preclinical antibacterial pipeline, WHO also aims to expand its work to encompass non-traditional products, bacterial vaccines and antifungals.
		Investor Action on AMR Initiative	Multiple	Established in January 2020, the Investor Action on AMR aims to leverage institutional investors to help combat AMR. Partners in the initiative are required to adopt a 'One Health' AMR lens within their investment decisions and engage companies they invest in on the risks, opportunities and impacts of AMR. Under the initiative, partners also commit to undertake at least one tangible outcome to help address AMR.
		Access to Medicine (ATM) Foundation Investor Engagement Activity	Multiple	The ATM Foundation supports investors to use the Access to Medicine Index and AMR Benchmark findings within investment processes. It does so by integrating company scores into stock valuations or proprietary sustainability frameworks and developing a framework for direct engagement with pharmaceutical companies on access to medicine and AMR issues. Over 100 institutional investors have signed an ATM Index Investor Statement. The ATM Foundation also coordinates collaborative investor engagement toward the achievement of the third UN Sustainable Development Goal.

B.3. IMPACT OF COVID-19 PANDEMIC

B3-1: IMPACT OF COVID-19 PANDEMIC ON INVESTMENT IN R&D FOR AMR-RELEVANT PRODUCTS AND/OR TECHNOLOGIES (N=53)



Source: RAND Europe analysis

B.4. ADDITIONAL LEARNING THEMES FROM THE COVID-19 PANDEMIC

1) Raising public awareness of risk and scaling up political will

The COVID-19 pandemic has increased public awareness about the risks and potential consequences of uncontrolled transmission of infectious diseases and highlighted the need for preparedness for future outbreaks. However, the scale, visibility and immediate urgency of COVID-19's impact on society differs from the AMR context, as the wider public still sees AMR as a less salient threat.

The level of media attention given to the AMR challenge is much lower than COVID-19, as is the visibility of political commitments, public awareness and knowledge about the risks and impact of AMR. Despite nearly 700,000 people dying every year due to AMR-related causes[1], AMR is not widely seen as a pandemic.

Learning from COVID-19 may apply to accelerating and scaling up efforts to communicate and raise awareness about the urgency of the AMR challenge amongst diverse communities globally. This includes raising awareness amongst the public, healthcare professionals and healthcare authorities, and engaging in enhanced communications and outreach to further escalate and scale up political commitments to tackling AMR globally to mitigate against future impacts.

2) Push and pull incentives to reduce risks of R&D and increase market viability

There may also be scope to learn from COVID-19 in the context of further advancing global efforts related to push and pull incentives for industry engagement with AMR R&D.

Industry also notes the need to learn from COVID-19 to ensure timely push incentives in some areas, such as vaccines, to increase the supply of products in development that could prevent infections from spreading and contributing to AMR. For example, the COVID-19 pandemic has shown that reactive funding for urgent public health threats is high risk and not aligned with efforts for preparedness and mitigation of crises. The pandemic also highlighted the role that proactive public funding can play in spearheading rapid innovation and mobilising industry engagement. Whereas AMR is a responsibility for actors across the public and private sectors, significant injections of public funding for AMR R&D would represent an important incentive from an industry perspective to reduce the risks and costs of R&D. They could also encourage collaborative working between industry, akin to what we witnessed with COVID-19 collaboration. It is important to recognise that large injections of public funding can also have implications for pricing negotiations.

1 O'Neill (2014).

As public funding is not a limitless resource, it would be important to carefully prioritise investments – including across different types of interventions such as diagnostics, vaccines, new antibiotics and alternative treatment approaches. As shown in the COVID-19 pandemic, diagnostics are key partners in the fight against infectious diseases; partnering with public-sector stakeholders is as important in encouraging diagnostic R&D as it is in preventative and therapeutic interventions. In the context of prioritisation, COVID-19 drug discovery and development efforts have entailed a mix of focusing on combinations of repositioned and repurposed medicines and R&D for new chemical entities. It is worth considering how the balance of novel R&D and R&D concerned with repurposing applies to the AMR agenda.

3) Regulation

The COVID-19 pandemic has shown that regulators can introduce flexibilities to support rapid and streamlined market access and that this can support R&D and approvals at pace. AMR is not unfolding as suddenly as the COVID-19 pandemic. However, regulation could have a role to play in reducing time to market for AMR-relevant products, provided that safety and effectiveness requirements are not compromised. Although requiring further research, some of the regulatory provisions which made a difference to the feasibility and pace of R&D during COVID-19 may also be important for scaling AMR-relevant R&D. Examples include enabling remote trials, rapid review for study protocol applications, rolling review of data from trials, accelerated assessment pathways for marketing authorisation of new products, accelerated review pathways for new indications for existing products. Applying learning from COVID-19 in relation to regulation around innovative clinical trial designs (e.g. non-inferiority and equivalence designs) is also relevant for AMR R&D, especially where placebo-based designs are not possible enrolment- or ethics-wise.

The positions related to IP protection and regulatory exclusivities for AMR-relevant products and/or technologies will also have a key role in incentivising innovation in this space. It is understandable and important to ensure equitable and affordable access to AMR-relevant products to populations globally, as is the intention behind the COVID-19 vaccine waiver, which prevents companies holding IP for COVID-19 vaccines from hindering production elsewhere. However, upfront clarity and early negotiations about IP-related practices can reduce uncertainties for industry in an innovation space where uncertainty acts as an additional disincentive.

4) Collaboration between diverse stakeholders

The COVID-19 pandemic has shown the importance of marshalling people with diverse professional backgrounds around a common focal area. In the COVID-19 context, this applies to company employees such as chemists, epidemiologists, clinicians, vaccine experts, virologists, biologists, pharmaceutical scientists and individuals working in different organisations in the public and private sectors. Bringing together multidisciplinary experts within individual companies to focus on AMR is also likely to matter.

The COVID-19 pandemic has also shown the potential of industry to collaborate while still maintaining appropriate competitiveness. For example, together with Takeda and VRI-Inserm, Janssen co-founded and co-leads the Corona Accelerated R&D in Europe (CARE) Consortium. The CARE consortium brings together pharmaceutical and academic research partners from 37 organisations across Europe, the US and China to advance coronavirus therapeutics R&D. Important questions remain to understand the incentives and enablers of such collaboration in the face of competitive dynamics and the extent to which such collaborative practices are scalable and applicable in the AMR space.

COVID-19 has also demonstrated the potential in collective action and collaboration between governments, academia and industry to tackle pressing public health challenges – not only on R&D fronts but also in relation to manufacturing, distribution and infrastructure such as cold chains, as well as in relation to surveillance and data sharing. Mobilising such cross-sector collaboration at scale is also important in the AMR context.

It is also worth reflecting on whether some (and if so, which) of the tools and infrastructure developed for COVID-19 may also apply to R&D efforts in the fight against AMR and can be sustained going forward.

5) Data-sharing practices

Data sharing is key to effective collaboration for healthcare R&D. The COVID-19 pandemic has reinforced the need for transparent and coherent frameworks for collecting, using and sharing data. This includes surveillance data on SARS-CoV-2 variants and early R&D that can enable shared understandings of the impact of variants on potential therapeutic effectiveness.

These types of data-sharing practices would also be relevant for 'staying ahead' of AMR – for example, to help characterise resistant bacteria to inform R&D priorities for industry. It will be important to learn about the enablers and challenges of data-sharing practices during COVID-19 in operationalising sustainable and widely acceptable data sharing in the AMR space at scale.

For example, how WHO's Global Antimicrobial Resistance and Use Surveillance System (GLASS) could be implemented nationally and supported by governments merits reflection in relation to tackling AMR. Sharing easy-access AMR surveillance data could also help inform local antimicrobial prescribing guidelines and practices. There is a need to consider industry commitment to sharing vital tools via open-source platforms with each other and the wider research community to help rapidly advance AMR-relevant R&D. Although some progress is being made in this space, there is a need to scale up efforts. For example, Pfizer's Antimicrobial Testing Leadership and Surveillance (ATLAS) database is open-access and offered as a fully searchable, interactive website and mobile application with data on bacterial sensitivity to various antibiotics and emerging resistance patterns. This resource can be accessed by decision-makers to help inform prescribing behaviours but could also help inform the targeting of R&D efforts. Platforms supported by artificial intelligence and blockchain technologies could also help support commercially sensitive data sharing between companies and are being considered for other areas of R&D (e.g. the platform MELLODDY – Machine Learning Ledger Orchestration for Drug Discovery).

B.5. LIST OF PRODUCTS AND SOURCES

This annex provides a series of tables listing the products or technologies being developed by Alliance members during the reporting period. Where this information is available, the tables also identify the pathogens targeted and the status of the pathogen on the CDC Biggest Threats list and WHO Priority Pathogen list. The information in these tables has been compiled using the following sources:

- The Pew Charitable Trusts' list of 'Antibiotics Currently in Global Clinical Development' (March 2021)
- The Pew Charitable Trusts' list of 'Non-traditional Products for Bacterial Infections in Clinical Development' (March 2021)
- The 'Medicines in Development - Antimicrobial Resistance' list (April 2021), and
- Alliance members' responses to the 2021 progress survey.

The tables present information on the following types of products or technologies:

- Antibiotics and antifungals
- Vaccines
- Diagnostic platforms and assays, and
- Non-traditional and other products[2].

Together, the tables demonstrate that 93 AMR-relevant products or technologies are currently being developed by Alliance members, comprising 54 antibiotics and antifungals, 12 vaccines, 13 diagnostic platforms and assays, and 14 non-traditional or other products. Broken down by sector, this comprises 29 products or technologies developed by R&D pharmaceutical companies, 50 by biotech/SMEs, 2 by generics companies and 12 by diagnostics companies.

2 Products and technologies classified as 'non-traditional and other' comprise those listed on The Pew Charitable Trusts' 'Non-traditional Products for Bacterial Infections in Clinical Development' list plus the following types of product or technology as reported by survey responses or on the Medicines in Development list: 'adjuvant – new chemical entity', 'antimicrobial (antiviral and antibacterial) and immunomodulatory', 'antibody', 'anti-virulence agent – new chemical agent' and 'nasal cell membrane modulator'.

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
Alaxia Pharma	Biotech/SME	ALX-009	*Pseudomonas aeruginosa, Achromobacter, Burkholderia spp.*	*Serious threats* - -	*Priority 1: critical* - -
Amplyx	Biotech/SME	Fosmanogepix (Gwt1 fungal enzyme inhibitor	*Candida*	*Serious threats*	-
Bioverys AG	Biotech/SME	BV100 (prev. Rifabutin)	*Acinetobacter baumannii*	*Urgent threats*	*Priority 1: critical*
		BV300	*ESKAPE and biothreat pathogens*	*Urgent threats*	*Priority 1: critical*
F. Hoffmann-La Roche AG.	R&D pharmaceutical	RG6006	*Acinetobacter baumannii*	*Urgent threats*	*Priority 1: critical*
GlaxosmithKline PLC	R&D pharmaceutical	Gepotidacin (GSK2140944)	*Staphylococcus aureus, Neisseria gonorrhoeae*	- *Urgent threats*	*Priority 2: high* *Priority 2: high*
		GSK2556286	*Mycobacterium tuberculosis*	*Serious threats*	-
		GSK3036656	*Mycobacterium tuberculosis*	*Serious threats*	-
		GSK3729098	*Mycobacterium tuberculosis*	*Serious threats*	-

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
Helperby Therapeutics PLC	Biotech/SME	HY-001	Gram negative Carbapenem resistant *Enterobacteriaceae,* Carbapenem resistant *Pseudomonas,* Carbapenem resistant *Acinetobacter*	*Urgent threats* *Serious threats* *Urgent threats*	*Priority 1: critical* *Priority 1: critical* *Priority 1: critical*
		HY-003	Gram negative carbapenem resistant *Enterobacteriacea, Pseudomonas*	*Urgent threats* *Serious threats*	*Priority 1: critical* *Priority 1: critical*
		HY-005B8a	Gram-positive including MRSA		*Priority 2: high*
		HY-006B7	Gram-negative resistant *Pseudomonas* and Gram-positive including MRSA	*Serious threats* -	*Priority 1: critical* *Priority 2: high*

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
		HY-009B2	Gram negative Carbapenem resistant *Enterobacteriaceae*	*Urgent threats*	*Priority 1: critical*
Johnson & Johnson	R&D pharmaceutical	SIRTURO® bedaquiline	*MDR- Mycobacterium tuberculosis*	*Serious threats*	-
Meiji Seika Pharma Co.	Biotech/SME	Nacubactam (OP0595)	*Klebsiella pneumoniae, Enterobacter spp, Pseudomonas aeruginosa*	- - *Urgent/serious threats*	- *Priority 1: critical* *Priority 1: critical*
		ME1100	-	-	-
MSD (known as Merck and Co. Inc in the US and Canada)	R&D pharmaceutical	Noxafil® Posaconazole	*Aspergillus*	*Watch list*	-
		RecarbrioTM (imipenem, cilastatin, relebactam)	-	-	-
		Sivextro® tedizolid	-	-	-
		Zerbaxa® ceftolozane and tazobactam	-	-	-
Mylan (now Viatris)	Generics	Pretomanid	*Mycobacterium tuberculosis*	*Serious threats*	-
Mylan (now Viatris)	Generics	Delamanid	*Mycobacterium tuberculosis*	*Serious threats*	-

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
Nabriva Therapeutics AG	Biotech/SME	ContepoTM (ZTI-01) Fosfomycin	-	-	-
	Biotech/SME	Xenleta® legamulin	*Staphylococcus aureus,* *Neisseria gonorrhoeae*	- *Urgent threats*	*Priority 2: high* *Priority 2: high*
Northern Antibiotics Ltd.	Biotech/SME	SPR741	Possibly: *Klebsiella pneumoniae, Acinetobacter baumannii, Enterobacter spp*	- *Urgent threats* *Urgent/serious threats*	- *Priority 1: critical* *Priority 1: critical*
NovaBiotics	Biotech/SME	Oral Lynovex	-	-	-
NovaBiotics	Biotech/SME	Inhaled Lynoxed	-	-	-
NovaBiotics	Biotech/SME	NP339	*Aspergillus fumigatus,* *Candida auris*	*Watch list* *Serious threats*	- -

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
Otsuka	R&D pharmaceutical	Delryba® delamanid	*Mycobacterium tuberculosis*	*Serious threats*	-
		OPC -167832 (DPrE1 inhibitor)	*Mycobacterium tuberculosis*	*Serious threats*	-
Paratek	Biotech/SME	Nuzyra® omadacycline	Non-tuberculous mycobacteria	-	-
Pfizer Inc.	Pharma	Aztreonam-avibactam (PF-06947387	-	-	-
Pfizer Inc.	Pharma	Ceftibuten + AV-006 (avibactam-prodrug)	MDR- *Enterobacteriaceae*	*Urgent threats*	*Priority 1: critical*
Scynexis	Biotech/SME	Ibrexafungerp	*Candida, Aspergillus*	*Serious threats* *Watch list*	-
Shionogi & Co. Ltd.	Pharma	Fetroja® cefiderocol	*Klebsiella pneumoniae, Acinetobacter baumannii, P. aeruginosa, Enterobacter spp.*	- *Urgent threats* *Serious threats* *Urgent /serious threats*	- *Priority 1: critical* *Priority 1: critical* *Priority 1: critical*

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
Spero Therapeutics LLC	Biotech/SME	Tebipenem/tebipenem pivoxil hydrobromide (SPR994)	*Klebsiella pneumoniae* *Acinetobacter baumannii* *Pseudomonas aeruginosa*	- *Urgent threats* *Serious threats*	- *Priority 1: critical* *Priority 1: critical*
		Tebipenem (SPR859)	-	-	-
		SPR206	*Klebsiella pneumoniae* *Acinetobacter baumannii* *Pseudomonas aeruginosa* *Enterobacter spp.*	- *Urgent threats* *Serious threats* *Urgent /serious threats*	- *Priority 1: critical* *Priority 1: critical* *Priority 1: critical*
		SPR720	Non-tuberculous mycobacteria, *Mycobacterium tuberculosis*	- *Serious threats*	-
TAXISpharma	Biotech/SME	TXA709/ TXA707	*Staphylococcus aureus*	-	*Priority 2: high*

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
Venatorx Pharmaceuticals Inc.	Biotech/SME	Cefepime + taniborbactam (VNRX-5133)	*Klebsiella pneumoniae, Pseudomonas aeruginosa, Enterobacter spp. Staphylococcus aureus*	- *Urgent threats* *Urgent /serious threats* -	- *Priority 1: critical* *Priority 1: critical* *Priority 2: high*
		PBP inhibitor Enterobacterales	*Enterobacterales*	*Urgent/serious threats*	*Priority 1: critical*
		PBP inhibitor Acinetobacter	*Acinetobacter*	*Urgent threats*	*Priority 1: critical*
		PBP inhibitor GC	*Gonorrhoea*	*Urgent threats*	*Priority 2: high*
		VNRX-7145 + ceftibuten	*Enterobacter spp.*	*Urgent /serious threats*	*Priority 1: critical*
Allecra Therapeutics	Biotech/SME	Exblifep (cefepime + enmetazobactam)	*Klebsiella pneumoniae, Enterobacter spp.*	- *Urgent/ serious threats*	- *Priority 1: critical*
Deinove	Biotech/SME	DNV3837/ DNV3681	*Clostridium difficile*	*Urgent threats*	-

AMR-RELEVANT ANTIBIOTICS AND ANTIFUNGALS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threat list**	**WHO Priority Pathogens list**
La Jolla Pharma	Biotech/SME	TP-271	*Staphylococcus aureus,* *Acinetobacter baumannii*	- *Urgent threats*	*Priority 2: high* *Priority 1: critical*
		TP-6076	*Klebsiella pneumoniae* *Acinetobacter baumannii,* *Enterobacter spp.*	- *Urgent threats* *Urgent/serious threats*	- *Priority 1: critical* *Priority 1: critical*
Microbion Corporation	Biotech/SME	Pravibismane (MBN-101)	-	-	-
MicuRx Pharmaceuticals Inc.	Biotech/SME	Contezolid (MRX-I)/contezolid acefosamil (MRX-4)	*Enterococcus faecium* *Staphylococcus aureus**	- -	*Priority 2: high* *Priority 2: high*
		MRX-8	*Klebsiella pneumoniae,* *Acinetobacter baumannii,* *Pseudomonas aeruginosa*	- *Urgent threats* *Serious threats*	- *Priority 1: critical* *Priority 1: critical*
Summit Therapeutics	Biotech/SME	Ridinilazole	*Clostridium difficile*	*Urgent threats*	

**Only for methicillin-resistant Staphylococcus aureus*

AMR-RELEVANT VACCINES IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threats list**	**WHO Priority Pathogens list**
GlaxoSmithKline PLC	R&D pharmaceutical	GSK2904545A	*Clostridium difficile*	*Urgent threats*	-
		Shigella4V (GSK4069327A)	*Shigella sonnei, Shigella flexeneri*	*Serious threats*	*Priority 3: medium*
		GSK3878858A	*Staphylococcus aureus*	-	*Priority 2: high*
Johnson & Johnson	R&D pharmaceutical	ExPEC4V (JNJ-63871860)	*Escherichia coli*	-	-
		COVID-19 vaccine	SARS-CoV-2	-	-
		ExPEC10V (JNJ-69968054)	*Escherichia coli*	-	-
MSD (known as Merck and Co. Inc in the US and Canada)	R&D pharmaceutical	V114	*Streptococcus pneumoniae*	-	*Priority 3: medium*
		V116	*Streptococcus pneumoniae*	*Serious threats**	*Priority 3: medium*
Pfizer Inc.	R&D pharmaceutical	PF-06425090	*Clostridium difficile*	*Urgent threats*	-
		GBS6 (PF-06760805)	Group B *Streptococcus*	*Concerning threats*	-
		SARS-CoV-2 vaccine	SARS-CoV-2	-	-
		20vPnC	*Streptococcus pneumoniae*	-	*Priority 3: medium*

* **Drug-resistant Streptococcus pneumoniae only*

AMR-RELEVANT DIAGNOSTIC PLATFORMS AND ASSAYS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name or description**	**Pathogens targeted**	**CDC Biggest Threats list**	**WHO Priority Pathogens list**
BD	Diagnostics	Antibiotic susceptibility testing	*Carbapenemase resistant organisms*	*Urgent threats*	-
	Diagnostics	Antibiotic susceptibility testing	*Carbapenemase resistant organisms*	*Urgent threats*	-
	Diagnostics	Antibiotic susceptibility testing	*Carbapenemase resistant organisms, MDR-Mycobacterium tuberculosis, Mycoplasma genytalium*	*Urgent threats Serious threats Watch list*	-
	Diagnostics	Antibiotic susceptibility testing	*Mycobacterium tuberculosis*	*Serious threats*	-
	Diagnostics	Antibiotic susceptibility testing	-	-	-
	Diagnostics	Antibiotic susceptibility testing	-	-	-

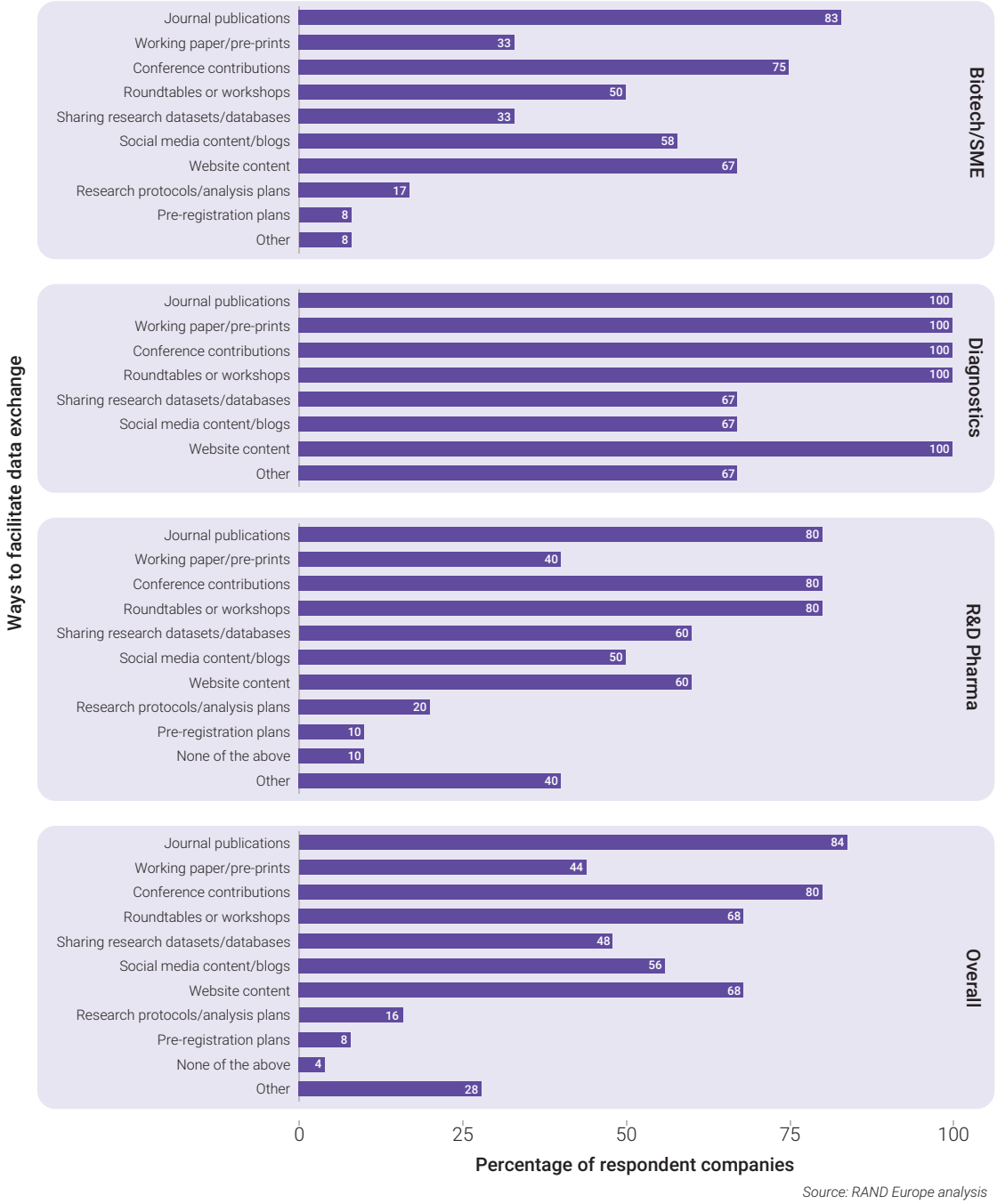
AMR-RELEVANT DIAGNOSTIC PLATFORMS AND ASSAYS IN CLINICAL DEVELOPMENT DURING THE REPORTING PERIOD					
Company	**Sector**	**Product/technology name or description**	**Pathogens targeted**	**CDC Biggest Threats list**	**WHO Priority Pathogens list**
bioMérieux SA	Diagnostics	VITEK 2	All pathogens	-	-
		VITEK MS (Mass Spectrometry)	All pathogens	-	-
		BioFire FilmArray panels	All pathogens	-	-
		ChromID media	-	-	-
		Virtuo	-	-	-
		Commercially sensitive	*Commercially sensitive*	*Commercially sensitive*	*Commercially sensitive*
Menarini Ricerche	R&D pharmaceutical	Syndromic platform for molecular testing	-	-	-

NON-TRADITIONAL AND OTHER AMR-RELEVANT PRODUCTS FOR BACTERIAL INFECTIONS IN CLINICAL DEVELOPMENT					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threats list**	**WHO Priority Pathogens list**
BioVersys AG	Biotech/SME	BVL-GSK098	*Mycobacterium tuberculosis*	*Serious threats*	-
		BV200	*Staphylococcus aureus*	-	*Priority 2: high*
Clarametyx	Biotech/SME	CMTX-101	Directed to a biofilm structure target that is highly conserved across most pathogenic bacteria, including Staphylococcus *aureus, Streptococcus pneumoniae, Pseudomonas aeruginosa, Klebsiella pneumoniae, Haemophilus influenzae, Escherichia coli, Enterobacteriaceae,* and *Acinetobacter baumannii*, among others.	*Serious threats*	*Priority 1: critical*
Da Volterra	Biotech/SME	DAV132	*Clostridium difficile*	*Urgent threats*	-
Destiny Pharma Ltd.	Biotech/SME	NTCD -M3	*Clostridium difficile*	*Urgent threats*	-
		XF-73 (exeporfiniumchloride)	*Staphylococcus aureus*	-	*Priority 2: High*
GlaxosmithKline PLC	R&D Pharmaceutical	GSK3882347	-	-	-
NovaBiotics	Biotech/SME	Nylexa	COVID-19, pneumonia and influenza	-	-
Peptilogics Inc.	Biotech/SME	PLG0206	-	-	-
Combioxin	Biotech/SME	CAL02	-	-	-

NON-TRADITIONAL AND OTHER AMR-RELEVANT PRODUCTS FOR BACTERIAL INFECTIONS IN CLINICAL DEVELOPMENT					
Company	**Sector**	**Product/technology name**	**Pathogens targeted**	**CDC Biggest Threats list**	**WHO Priority Pathogens list**
iNtRON Biotech/ SMEnology Inc.	Biotech/SME	N-Rephasin (SAL200) (Tonabacase)	*Staphylococcus aureus*	-	*Priority 2: high*
Rebiotix	Biotech/SME	RBX2660/ RBX7455	-	-	-
Synthetic Genomics	Biotech/SME	Ribaxamase (SYN-004)	*Clostridium difficile*	*Urgent threats*	-
Contrafect	Biotech/SME	Exebacase	*Staphylococcus aureus*	-	*Priority 2: high*

B.6. TYPES OF DATA-SHARING ACTIVITIES

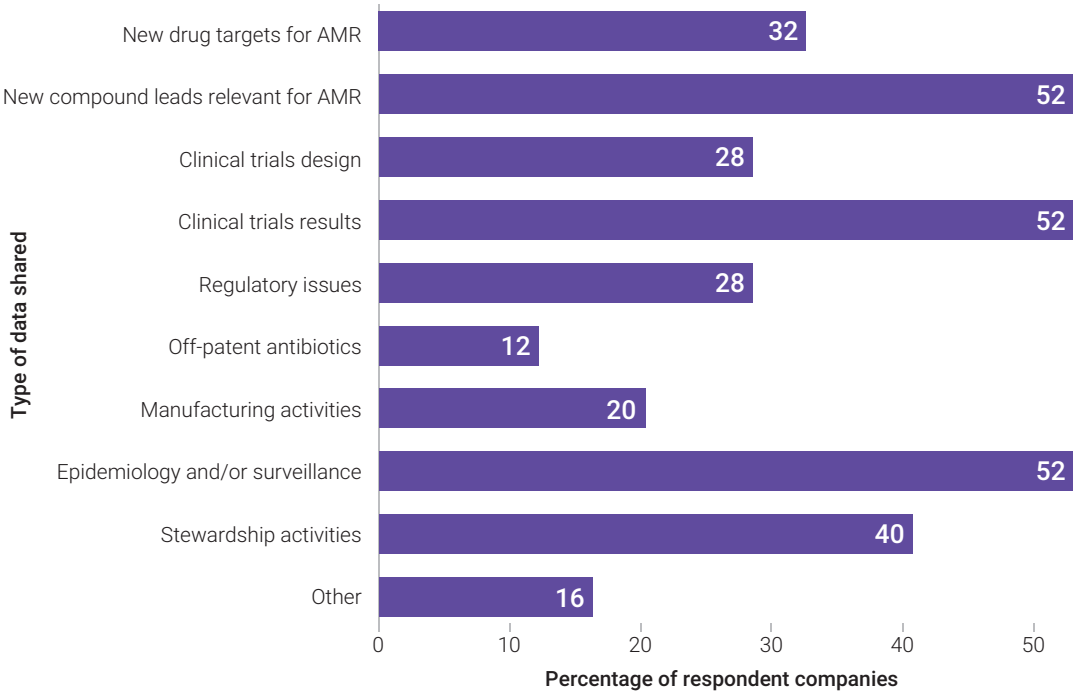
B6-1: TYPES OF DATA-SHARING ACTIVITIES FOR COMPANIES THAT REPORTED ANY DATA SHARING AND/OR EXCHANGE OF INFORMATION (N=25)



Source: RAND Europe analysis

B.7. TYPES OF DATA SHARED

B7-1: TYPES OF DATA SHARED BY COMPANIES THAT REPORTED ANY DATA SHARING AND/OR EXCHANGE OF INFORMATION (N=25)



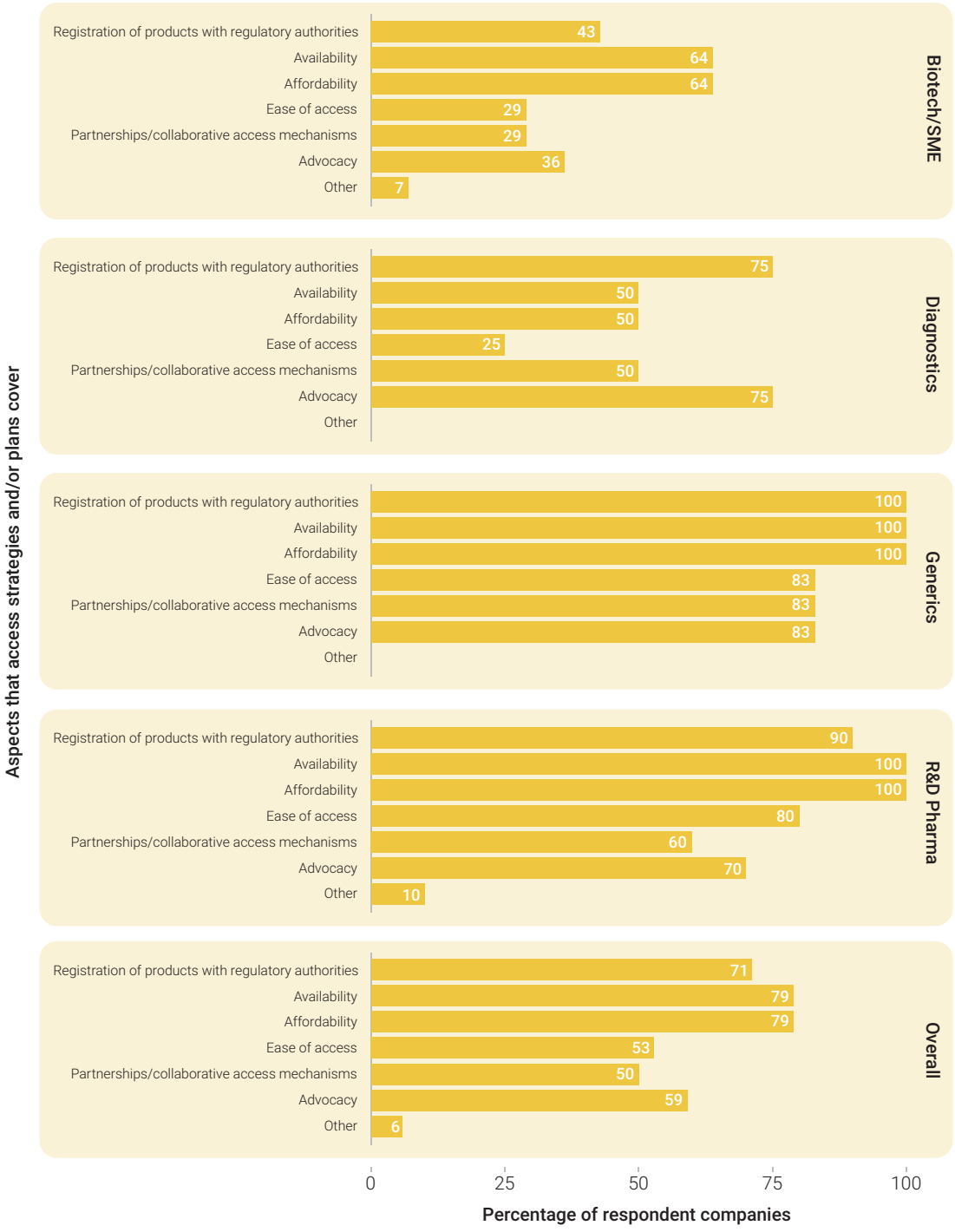
Source: RAND Europe analysis

Annex C. Additional information on access

C.1. BREAKDOWN OF AREAS COVERED BY ACCESS STRATEGIES AND PLANS OF AMRIA MEMBER

Access strategies or plans for AMR-relevant products or technologies most frequently covered issues related to the availability of products or technologies, with the majority of Alliance member respondents who had access strategies or plans in place focusing on these areas. Half or more of alliance members strategies or plans also covered advocacy – for example, advocacy for effective regulatory approval processes and ensuring product quality, advocacy for the inclusion of new diagnostics tools in healthcare guidelines and advocacy related to appropriate use; ease of access, partnerships/collaborative access mechanisms (Figure C1).

FIGURE C1-1: ASPECTS COVERED BY COMPANY ACCESS STRATEGIES AND/OR PLANS



Source: RAND Europe analysis

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