



## ANNEX A2

Additional information  
on methodology





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

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

# Section 1: Survey instrument

## THE FOURTH AMR INDUSTRY ALLIANCE SURVEY ON INDUSTRY CONTRIBUTIONS TO THE FIGHT AGAINST ANTIMICROBIAL RESISTANCE

### PROJECT INFORMATION SHEET

#### The context

Welcome to the 2023 Antimicrobial Resistance (AMR) Industry Alliance survey on the contributions of Alliance members to the fight against AMR. RAND Europe, a not-for-profit policy research institute, has developed the survey in collaboration with the AMR Industry Alliance.

The survey aims to assess the progress of AMR Industry Alliance members in tackling AMR. More specifically, the survey seeks to:

- **Demonstrate industry contributions and achievements** in the fight against AMR in an evidence-based and credible way.
- **Learn about the progress made** since prior survey rounds.
- **Ensure sector accountability** to target audiences, i.e. policymakers and the informed public.

The survey's findings will be analysed to produce the fourth AMR Industry Alliance Progress Report. We are committed to ensuring the report can have an impact and have designed the survey with this end goal in mind.

In order for the report and its findings to have the desired impact on target audiences, it is important to provide a credible account of sector activities. We greatly appreciate your support with this effort and hope you will also benefit from the outputs of the report.

This survey has been adapted from prior rounds to provide a focus on core questions while also enabling the continuity needed to be able to understand progress over time (where this can meaningfully be reflected upon). The adaptations have enabled a more focused and streamlined survey.

## Organisation of the survey and contents

The survey is organised into four sections, as follows:

1. Company profile information.
2. Questions related to AMR-relevant **Research and Science (R&S)** metrics.
3. A focus on a small number of key, prioritised questions related to **(a) access metrics** and **(b) stewardship and appropriate use metrics**.
4. Questions related to **manufacturing and environment metrics** (applicable to Research & Development [R&D] pharmaceuticals and generics companies only. You will not be asked to complete this section if your primary affiliation is to the biotech/Small and Medium Enterprises [SMEs] or diagnostics sector).

When completing the survey, please note some general guidance:

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, Respiratory syncytial virus [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, traditional approaches and others, and this is detailed in the questions in the survey).
- For all questions apart from those 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 for the current survey is 1 April 2021 to 31 March 2023 for most questions.
- For questions related to the levels of financial investment, we will be asking about the levels of your company's financial investment in two time periods: (a) financial year 2021 and (b) financial year 2022. The purpose of asking for levels of financial investments for both of these financial years is to capture investments since the last reporting timeframe for the AMR Industry Alliance survey, as well as to allow us to understand changes over time.

Please note that detailed information and guidance for each question are provided within the body of the survey sections you will be completing on the SmartSurvey platform. RAND Europe uses the SmartSurvey platform for most of our survey-related projects. SmartSurvey is ISO27001 certified and fully compliant with the internationally recognised standard for the information security management system (ISMS) and Cyber Essentials Plus certified.



A supportive information document, with links to sources of information you may want to consult to help your company complete the survey, can be downloaded [here](#).

If you are completing the survey in more than one go, please make sure to click the save button before closing. In the SmartSurvey platform, you will find a button at the end of the page you are viewing with the phrase 'Save and Continue Later' that allows you to save progress on the survey up to the page you are viewing. You will then be sent a link by SmartSurvey that allows you to continue submitting answers to the survey questions from that point onwards. You will need to use that new link when you resume completing the survey.

We recommend that one person in each company inputs all data into the survey portal (even if others contribute the data inputs in other document formats). However, should your company wish for more than one person to input data directly into the survey portal, the primary named contact for the survey completion in each company will need to coordinate this to ensure each person has the most recent and relevant link to the survey.

For technical support during the process of completing this survey or for general enquiries related to the survey, please contact: [AMRIA2023survey@randeurope.org](mailto:AMRIA2023survey@randeurope.org)

## How will the survey data be used?

The questions will be analysed at the level of a sector (i.e. R&D pharmaceuticals, biotech/ SME, diagnostics or generics) and the AMR Industry Alliance as a whole, and insights will be shared in aggregate form in the public Progress Report rather than at the level of an individual company. Throughout the sections, there will be a few questions that ask you to clarify an answer with a further narrative response. You are asked not to disclose confidential and commercially sensitive information as part of the narrative you share; even though the answers will not be linked to your company in public reporting, they may be shared in aggregate and synthesised form.

Information collected in the survey will be held and managed by RAND Europe. The survey platform – SmartSurvey – will be operated by RAND Europe.

*If* you consent to take the survey, the AMR-Industry Alliance Secretariat as the client may receive de-identified answers (e.g. with a unique identifier linking questions, such as Company 1, Company 2, Company 3) but not answers linked to the name of your company. Documents attributing survey responses to your company shall be maintained in the strictest confidence by RAND.

An additional confidentiality agreement regarding the use of your survey responses is available for download and signature if you choose to do so [here](#). This is not essential, but if you choose to do so, a signed copy should be sent to: [AMRIA2023survey@randeurope.org](mailto:AMRIA2023survey@randeurope.org)



# Privacy notice

## ABOUT THE PROJECT

Antimicrobial resistance (AMR) is a key global public health challenge. It impacts medical procedures, efforts to control infectious diseases and the safety, security and sustainability of our food systems and supply chains. Industry has a key role to play in efforts to try to combat AMR, together with other stakeholders such as governments, international organisations, academia, healthcare professionals, civil society, and others. Against this context, the AMR Industry Alliance was formed in 2017 and brings together over 100 biotechnology, diagnostic, generics and R&D pharmaceutical companies and trade associations in the fight against AMR. The AMR Industry Alliance is committed to doing so through activities related to four areas of commitment: research and science, appropriate use, access, manufacturing and environment. To assess progress towards achieving these commitments, the AMR Industry Alliance conducts an annual survey of its members.

The current survey, which you are invited to complete, focuses especially on the (i) Research and Science and (ii) Manufacturing and the Environment pillars. The survey also includes some key questions on activities related to (iii) Access and (iv) Appropriate use and Stewardship, as these themes complement the R&D activity of some AMR Industry Alliance members.

## WHO IS CONDUCTING THIS RESEARCH?

RAND Europe is a not-for-profit research Institute based in Cambridge. RAND Europe has been commissioned to conduct the third survey round and to produce a public report to capture learnings and share insights about industry contributions in the fight against antimicrobial resistance since the last reporting period.

## WHAT PERSONAL DATA ARE WE COLLECTING?

RAND Europe is collecting, as part of the profile section of the survey, personal information on the individual responding to the survey on behalf of the company, including name, company, role in the company, postal address, contact email and telephone number.

## HOW ARE WE COLLECTING AND SHARING PERSONAL DATA?

RAND Europe will collect this information via the company profile section of the survey on the SmartSurvey platform. The AMR Industry Alliance Secretariat has provided RAND Europe with your names and contact details to enable us to distribute the survey to you for completion.

## WHY ARE WE COLLECTING IT?

This information is being collected in case there is a need for clarification on any of the responses provided by the individual completing and coordinating the completion of the survey on behalf of the company.

## WHAT IS THE LEGAL BASIS FOR PROCESSING YOUR DATA?

It is our legitimate interest to obtain and retain information on your name and function (i.e. organisational affiliation and role), as this is necessary to facilitate contact with you and it would be reasonable to anticipate that you expect this. As your personal details will not be linked to your company's responses for the project, we have assessed that such use does not affect your rights or freedoms.

## WHAT ARE WE USING THE DATA FOR?

This information is being collected in case we need to contact you regarding survey-related clarifications.

## HOW DO WE KEEP YOUR DATA SECURE?

The research team at RAND Europe have put appropriate security measures in place to keep personal data secure and to prevent any unauthorised access to or use of them. The research team will collect and store all data in accordance with the Data Protection Act (2018) and General Data Protection and Regulation (GDPR) requirements. Data will be stored on secure servers.

## HOW LONG DO WE KEEP YOUR DATA?

Your data will be retained for up to one year after the project has been completed and published.

## YOUR LEGAL RIGHTS

RAND Europe operates in accordance with EU law, including GDPR. You are provided with certain rights that you may have the right to exercise through us. In summary, those rights are:

- (1) To access, correct or erase your data
- (2) To object to the processing of your data
- (3) To request that our processing of your data is restricted
- (4) To request that your data be transferred
- (5) To withdraw your consent for us to process your data.

If you wish to exercise any of these rights, please contact the RAND Europe Data Protection Officer by email at [REdpo@randeurope.org](mailto:REdpo@randeurope.org) or in writing to Data Protection Officer, RAND Europe, Westbrook Centre, Milton Road, Cambridge, CB4 1YG, UK.

## Consent to participate in the survey

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/ Small-Medium Enterprises (SMEs)	Diagnostic companies
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

**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 before the pre-submission of my completed survey without giving any reason, and 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 that are members of the AMR Industry Alliance and that took part in the survey.

- 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 de-identified and not at the 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 de-identified and not at the company level.

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

**7.** I confirm, on behalf of my company, that de-identified answers (e.g. with a unique identifier linking a company, such as Company 1, Company 2 and 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.

- Yes
- No

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

- Yes
- No

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

**10.** 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
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

**11.** Please provide your company name

**12.** Please select the code provided in your invitation email to participate in the survey – it is very important that you put the correct code so that you are asked questions that apply to your specific sector and are relevant to your company (four digits).

Drop down box with options: RDP1, GNR2, BTH3, DGN4:

**13.** Please provide the information below for the key contact 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 case we need to get in touch for any clarifications in relation to your submission.*

Name

Role

Email

**14.** Where are your company's AMR-related activities 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 [here](#).*

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

# Section 1: R&D

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

Guidance for this section:

This section of the survey refers to your company's investment and activities in R&D for AMR-relevant pathogens. It is divided into five 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;

We will be asking about the levels of your company's financial investment in two time periods: (a) financial year (FY) 2021 and (b) FY 2022. 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.

For all other questions (i.e. those not related to levels of financial investment), the reporting timeframe is **between 1 April 2021 and 31 March 2023**, which covers your activities since the last survey reporting round. 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 World Health Organization's (WHO's) priority pathogen list and/or the Center for Disease Control and Prevention's (CDC's) Antibiotic Resistance (AR) Threats Report but is not confined to pathogens on these lists alone. For a link to the [WHO priority pathogen list please click here](#). For the [CDC AR Threats report please click here](#).

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, respiratory syncytial virus (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).

Investments made by your company into AMR-relevant R&D in-house (i.e. internal investments) are in scope and should be included. Investments made into AMR-relevant R&D externally (e.g. into partnerships and investments into the R&D of other companies) are not in scope and should not be included.

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 and R&D on off-patent products) are within scope.

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

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

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

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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.

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 and R&D on off-patent products) are within scope.

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

Investments made by your company into AMR-relevant R&D in-house (i.e. internal investments) are in scope and should be included. Investments made into AMR-relevant R&D externally (e.g. into partnerships and investments into R&D of other companies) are not in scope and should not be included.

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

### 15. Did your company invest in R&D for AMR-relevant products and/or technologies in the Financial Year (FY) 2021 and FY 2022?

- Yes
- No

**16. How much did your company invest in R&D for AMR-relevant products and/or technologies in FY 2021 and FY 2022?** (For each FY, tick one of the options below).

Guidance:

For companies with investment levels over US\$20m, we request that you provide a specific figure in US\$, rounded to the nearest million in the comment box provided. Please make clear which financial year the value is for. For companies with investment levels under US\$20m, it is optional to provide a specific figure in US\$ in the comment box provided.

	Less than US\$1m	US\$1–5m	US\$6–10m	US\$11–15m	US\$16–20m	Over US\$20m: please specify the exact figure rounded to the nearest million in the comment box
FY 2021						
FY 2022						

Please specify the exact amount per year (i.e. for FY 2021 and FY 2022) rounded to the nearest million (required/mandatory if over US\$20m). (Word limit 250 words):

**17. In comparison to FY 2020, did your company's investment in R&D for AMR-relevant products and/or technologies in FY 2021** (tick one option):

Guidance:

For companies that replied to the previous progress report, you may consider referring to your data submitted for FY 2020.

- 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%)

**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).

	Decrease investment	Maintain the 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 reduce prices further increase and 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
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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 between 1 April 2021 and 31 March 2023. 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 between 1 April 2021 and 31 March 2023 was made as the key interest of the AMR Industry Alliance is in understanding activity since the last reporting period.



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 and R&D on off-patent products) are within scope.

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

Investments made by your company into AMR-relevant R&D in-house (i.e. internal investments) are in scope and should be included. Investments made into AMR-relevant R&D externally (e.g. into partnerships and investments into R&D of other companies) are not in scope and should not be included.

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

**19. What stages of R&D for AMR-relevant products and/or technologies did your company invest in between 1 April 2021 and 31 March 2023?** (Please indicate the number of AMR-relevant products and/or technologies for each stage of R&D in which your company has invested).

Guidance:

We request that you provide a number in each line below. If your company did not invest in any stages of R&D for AMR-relevant products between 1 April 2021 and 31 March 2023, 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 31 March 2023.

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 (word limit 250 words):

**20. For what types of AMR-relevant products and/or technologies did your company invest in R&D between 1 April 2021 and 31 March 2023?** (Please indicate the number of AMR-relevant products and/or technologies in each case).

*Guidance:*

*We request that you provide a number in each line below. If your company did not invest in any type of AMR-relevant product and/or technology between 1 April 2021 and 31 March 2023, 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.*

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 and new/adapted formulations for use in specific patient populations or new delivery methods)

AMR-relevant vaccines (e.g. novel vaccines, adapted dosage approaches and 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 and antibody-antibiotic conjugates)

New diagnostic platforms or assays

Repurposed/new applications of existing diagnostic platforms or assays

Software, hardware or middleware

Tools for AMR surveillance and/or epidemiology research

Other (please specify in the comment box below)

Please specify if 'Other' was selected above (word limit 250 words):

**21. What types of collaborations for AMR-relevant R&D did your company engage in between 1 April 2021 and 31 March 2023?** (Tick all that apply):

- Partnerships with country-level government bodies
- Partnerships with academic institutions
- Partnerships with other private sector/industry organisations
- Other (e.g. public-private partnerships, other international organisations, not-for-profits/charities, non-governmental organisations or foundations. Please specify in the comment box below (word limit 250 words):

## 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
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

*Guidance:*

*In this sub-section, we will inquire about the challenges facing investment in AMR-relevant R&D that your company has faced in the reporting period of 1 April 2021 to 31 March 2023.*

*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.*

**22. On a scale of 1 to 4, to what extent did the following factors present a challenge to your company's investment levels/decisions in R&D for AMR-relevant products and/or technologies between 1 April 2021 and 31 March 2023?** We are considering the factors in the context of challenges.

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
<b>Lack of appropriate package of pull incentives/instruments in general – either in scale or nature of incentives (e.g. advanced market commitments/guaranteed purchase funds, valuation mechanisms, reimbursement mechanisms)</b>					

	1 No influence	2 To a small extent	3 To a moderate extent	4 To a large extent	Do not know
Market viability concerns related to a lack of clear and stable market size and/or uncertain prescriber and/or payer behaviours					
Historical sales volumes (e.g. low volumes as a challenge) influencing investments going forward					
Regulation challenge: the 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)					
Challenges related to the availability of needed skills and capabilities for AMR-relevant R&D activities					
Inability to identify and/or form appropriate collaborations needed for R&D					
Risk of R&D/scientific failure for AMR products/technologies					
COVID-19's 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 the comment box below)					

Please specify challenges if 'Other' was selected above (word limit 250 words):

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

	1 No influence is likely	2 Would influence to a small extent	3 Would influence to a moderate extent	4 Would influence to a large extent	Do not know
Improving mechanisms that support access/availability, including valuation models for novel products and/or technologies to capture full societal benefits and changes in reimbursement models to support patient access to novel antibiotics					
Stronger mechanisms that incentivise innovation, i.e. pull incentives (e.g. sufficiently sized subscription models, market entry award payments; transferrable patent exclusivity extensions; guaranteed purchase funds/advanced market commitments)					
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					
Improved push incentives (e.g. greater availability of public grant funding, tax credits for AMR-relevant R&D)					
Other (please specify in the comment box below)					

Please specify if 'Other' was selected above (word limit 250 words):

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

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Guidance:

*In this sub-section, we seek to understand whether your company discontinued any AMR-relevant R&D programmes between 1 April 2021 and 31 March 2023.*

### 24. Did your company discontinue any AMR-relevant R&D programmes between 1 April 2021 and 31 March 2023?

- Yes
- No

### 25. What are the key reasons your company discontinued AMR-relevant R&D programmes between 1 April 2021 and 31 March 2023? (Tick all that apply):

- Due to the high costs of R&D coupled with other company priorities
- Poor market conditions, making the likelihood of a viable market unlikely
- Difficulties in accessing required partners/collaborators
- Scientific reasons (e.g. lack of efficacy in intended indications shown as R&D progressed, inability to achieve targeted product profiles, concern that products under development would not offer solutions to unmet medical needs)
- Difficulties in recruitment to clinical trials
- Other

Please specify if 'Other' was selected above (word limit 250 words):



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

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Guidance:

*In this sub-section, we will inquire about whether and how you facilitated data sharing and exchange with external organisations/individuals between 1 April 2021 and 31 March 2023 as it relates to AMR-relevant activities.*

*The types of data shared and exchanged can be diverse, e.g. data related to new drug targets, new compound leads, clinical trials, data relevant to regulatory aspects, off-patent antibiotics, manufacturing-related activities, surveillance and epidemiological data, data related to stewardship activities or other. Data sharing and exchange can occur through journal publications, conferences and 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.*

**26. Did you facilitate data sharing and/or exchange of information related to R&D for AMR-relevant products and/or technologies between 1 April 2021 and 31 March 2023? (Tick one option):**

- Yes
- No



**27. What AMR-relevant activities did your company share data on between 1 April 2021 and 31 March 2023?** (Tick all that apply):

- Data related to new drug targets relevant to AMR
- Data related to new compound leads relevant to AMR
- Data related to clinical trial design
- Data related to clinical trial 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; word limit 250 words):

# Section 2: A) Access efforts B) Appropriate use and stewardship efforts

## Section 2 Sub-section A: Access-related activities

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

Guidance for this section:

*This section of the survey asks four brief questions related to your company’s activities around issues related to access to AMR-relevant products and/or technologies.*

*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, efforts related to advocacy on access-related issues, and efforts related to reducing the prevalence of substandard and/or falsified products/technologies to ensure access to quality products/technologies.*

*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. For a link to the WHO priority pathogen list, please click [here](#). For the CDC AR Threats report, please click [here](#).*

*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 from 1 April 2021 to 31 March 2023.

**28. Between 1 April 2021 and 31 March 2023, did your company implement any activities related to supporting access to AMR-relevant products and/or technologies?**

- Yes
- No

**29. For which of the following did your company undertake activities to support access to AMR-relevant products and/or technologies between 1 April 2021 and 31 March 2023?**

(Tick all that apply):

Guidance:

In responding to this question, please refer to the World Bank income classifications, available [here](#).

- 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

**30. Did your company engage in the following types of activities to support access to AMR-relevant products and/or technologies between 1 April 2021 and 31 March 2023 address?**

(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, e.g. 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 the appropriate use of products and/or technologies, etc.)
- Reducing the prevalence of substandard and/or falsified products/technologies to ensure access to quality products/technologies (e.g. enhancing product safety through tamper-proof packaging and/or serialisation, raising awareness about the risks of using substandard and falsified products and/or technologies, monitoring supply and distribution channels, improved inspections of supply and distribution channels, establishing counterfeit management teams; improving quality management systems and controls, working with other organisations/agencies to raise awareness of counterfeiting)
- None of the above
- Other (please specify; word limit 250 words):

**31. Were diversity, equity and inclusion considerations explicit in your company's access-related plans and/or strategies relevant to activities conducted between 1 April 2021 and 31 March 2023?**

- Yes
- No
- Do not know

## Section 2 Sub-section B: Appropriate use and stewardship of antimicrobials

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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 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 1 April 2021 and 31 March 2023.*

*Consistent with the definitions used by the WHO and the CDC, the Alliance defines the 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 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.*

### **32. Between 1 April 2021 and 31 March 2023, did your company implement activities related to appropriate use and stewardship for AMR-relevant products and/or technologies?**

(Tick one option):

- Yes
- No

**33. Between 1 April 2021 and 31 March 2023, did your company's activities related to 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 [here](#).

- 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

**34. Between 1 April 2021 and 31 March 2023, which of the following areas did your appropriate use and stewardship activities that you implemented 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 activities related to vaccine R&D or access issues
- Supporting early, appropriate and/or expanded use of diagnostics to prevent antimicrobial misuse (e.g. deploying diagnostics for pathogen identification and/or antimicrobial susceptibility/resistance testing)
- Generating evidence and tools to support appropriate use and stewardship (e.g. real-world clinical evidence regarding use and potential benefits or risks of a medical product and/or technology, evidence from investigator-led studies, software to support decision-making around prescribing and adherence)
- 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 the appropriate use of products and/or technologies, etc.)





Reducing the prevalence of substandard and/or falsified products/technologies to ensure access to quality products/technologies (e.g. enhancing product safety through tamper-proof packaging and/or serialisation, raising awareness about the risks of using substandard and falsified products and/or technologies, monitoring supply and distribution channels, improved inspections of supply and distribution channels, establishing counterfeit management teams; improving quality management systems and controls, working with other organisations/agencies to raise awareness of counterfeiting)

None of the above

Other (please specify; word limit 250 words):

**35. Were diversity, equity and inclusion considerations explicit in your company's appropriate use and stewardship-related plans and/or strategies relevant to activities conducted between 1 April 2021 and 31 March 2023?**

Yes

No

Do not know



## Section 3: Manufacturing and the Environment

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

Guidance for this section:

This section of the survey refers to your company's activities around controlling antibiotic discharge into the environment through your manufacturing and supply-chain processes. More specifically, the purpose of this survey section is to establish the extent of Alliance Manufacturing Members' progress against Alliance members' commitment to driving the implementation of the [Common Antibiotic Manufacturing Framework](#) and [Predicted No-Effect Concentration \(PNEC\) targets](#) across their global supply chains (including company-owned and supplier sites). The survey covers the two years since the last survey, i.e. the timeframe we are now asking you to consider reflects the period starting 1 April 2021 through to 31 March 2023.

As per the prior survey round, 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 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 PNEC targets. In addition, there are a few questions embedded in the survey sections, which are forward-looking – they ask for information relating to anticipated timeframes and rationale for product certification in light of the recent publication of the [Common Antibiotic Manufacturing Standard](#). This standard was published by the AMR Industry Alliance in 2022 and formalised the AMR Industry Alliance 2018 Common Antibiotic Manufacturing Framework.

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 the 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 supplies 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(s) and/or drug product(s). Second and third-tier suppliers are out of scope.

The section refers to the Common Antibiotic Manufacturing Framework and the list of PNEC targets developed by Alliance members. We also provide an [Excel spreadsheet](#) to assist you in completing the survey. This sheet provides you with the different criteria found in the Common Antibiotic Manufacturing Framework for manufacturing sites. Further details on how to complete it are provided next to the relevant questions in the survey sections that follow.

As a reminder, your responses are confidential. RAND Europe, the survey administrator, will only report aggregated data (at the sector and Alliance level) to the Alliance and in a public report.

## Section 3 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

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 [PNEC targets](#). By your own antibiotic manufacturing sites, we mean sites under the direct control or ownership of the company in which an antibiotic API and/or drug product (i.e. formulated products) is manufactured.

In the previous progress report survey, you were provided with guidance to assess the extent to which your sites 'fully meet', 'partially meet' and 'do not meet' the Common Antibiotic Manufacturing Framework and the list of PNEC targets. You 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, and we ask that you submit anonymised findings from the evaluation of your different sites. The [Excel spreadsheet](#) that accompanies this survey explains the different criteria found in the Common Antibiotic Manufacturing Framework for manufacturing sites and will assist you in answering the questions in this survey section. The [Excel spreadsheet](#) should be completed and sent to [AMRIA2023survey@randeurope.org](mailto:AMRIA2023survey@randeurope.org). 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 completing the spreadsheet 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. Your completed spreadsheet will be used by the research team to analyse the findings and will not be shared with the Alliance Secretariat in a way that links the data at the company level.

Based on the information you complete in the [Excel spreadsheet](#), the survey questions that follow allow you to submit an aggregate status of your sites (e.g. 'How many of your own manufacturing sites meet the Common Antibiotic Manufacturing Framework requirements?').

These are in the body of the survey below.

**36. As of 31 March 2023, how many of your own antibiotic manufacturing sites do you have?**

**37. As of 31 March 2023, how many of your own antibiotic manufacturing sites have been assessed against the criteria in the Common Antibiotic Manufacturing Framework in the last five years** (where the assessment has been done through an audit performed in accordance with the requirements of the Framework)?

Guidance:

The Common Antibiotic Manufacturing Framework requires auditing of manufacturing sites at least every five years to ensure that antibiotics manufacturing facilities (including APIs and formulation) minimise their environmental impact. As part of the program, companies are asked to conduct external site tours/reviews of their own manufacturing sites to verify that operating conditions and practices are in place and appropriately followed.

As defined in the Common Antibiotic Manufacturing Framework, by 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; (vi) waste and wastewater disposal records. If the review processes (site and exterior) consider all of the items listed in the guidance above, they are considered to be adequate. If the reviews are deficient in one or more of the items listed in the guidance above, they are considered to be inadequate.

Note: The number you put into the box below as your answer must be equal to or lower than the overall number of owned manufacturing sites you reported having in the previous question.

**38. As of 31 March 2021, among your own antibiotic manufacturing sites that have been assessed against the criteria in the Common Antibiotic Manufacturing Framework in the last five years, please provide the following information on the extent to which the sites meet the Framework requirements:**

Guidance:

We request that you 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 spreadsheet](#) provided to you 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 spreadsheet](#) 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 spreadsheet](#) for 'own manufacturing sites' must be answered with the drop-down option 'no' or 'do not know'.

To assess the extent to which your sites meet the requirements of the Common Antibiotic Manufacturing Framework, we encourage you to first complete your evaluation in the [Excel](#).

[spreadsheet](#) 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. Doing so will enable you to effectively answer the question and fill in the boxes below. The sum of your answer should equal the number of owned manufacturing sites that have been adequately assessed against the criteria in the Common Antibiotic Manufacturing Framework in the last five years that you provided an answer for in the previous question. Please check that this is the case.

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

How many of your own sites **partially meet** the Common Antibiotic Manufacturing Framework requirements?

How many of your own sites **do not meet** the Common Antibiotic Manufacturing Framework requirements?

**39. What actions did your company take between 1 April 2021 and 31 March 2023 to ensure that your own antibiotic manufacturing sites meet the Common Antibiotic Manufacturing Framework requirements?** (Please tick all that apply):

*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.*

- Developed and implemented improvement plans to help own sites meet expectations of the framework.*
- Implemented operating procedures (e.g. changed equipment/room cleaning method, separately treated certain waste streams, etc.) to help ensure own sites met expectations of the framework.*
- Providing training to support improvement practices in own sites to meet expectations of the framework*
- Added additional wastewater treatment capacity and/or different wastewater treatment technology*
- No action was taken*
- Other (please specify in the box below; word limit 250 words):*

**40. As of 31 March 2023, how many antibiotic products are manufactured at your own sites?**

Guidance:

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(s) and drug product(s), 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, it counts as two 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 three different owned manufacturing sites, then this is counted as three products (again, because three different assessments of PNEC adherence will be performed, one per site).

**41. 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 minimising selective pressure on bacteria in the receiving water body to mutate (and thus minimise the 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](#).

**42. As of 31 March 2023, of the antibiotic products manufactured at your own sites 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 minimising selective pressure on bacteria in the receiving water body to mutate (and thus minimise the 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](#). Your answer assumes that all the products you report on in your answer below have both been assessed against PNEC targets and meet the targets. The answer should be either equal to or lower than the number provided in the previous question. Please check that this is the case.





**43. What actions did your company take between 1 April 2021 and 31 March 2023 to ensure that your own antibiotic manufacturing sites' products meet the PNEC targets?** Please select from the options below (tick all that apply):

- Performed Mass balance (for all compounds)
- Performed Mass balance (for some compounds)
- Performed sampling and analysis (for all compounds)
- Performed sampling and analysis (for some compounds)
- Dry/vacuum cleaning of production area(s)
- Collected equipment rinses and treated separately (not to water)
- Added additional wastewater treatment technology (revenue expense)
- Added additional wastewater treatment technology (capital expense)
- No action was taken
- Other (please specify in the box below, word limit 250 words):

**44.** The AMR Industry Alliance published the [Antibiotic Manufacturing Standard](#) in 2022 and this standard formalises the AMR Industry Alliance 2018 Common Antibiotic Manufacturing Framework. **In consideration of the anticipated launch of the Certification Scheme in the second quarter of 2023, we are interested in understanding your company's intent in relation to seeking product certification for products made at your own sites through the scheme.\***

Please tick the one answer that best applies to your overall intent:

*Guidance: We are asking about your intentions, not commitments, at this stage.*

- We will seek to certify all our products over time
- We will seek to certify some but not all of our products over time
- Will not seek to certify any of our products
- We have not yet thought about our intentions in relation to product certification

**45. Please provide a brief clarification of your rationale as it relates to your certification intentions for products made at your own sites, based on the answer reported in the prior question\* (word limit 250 words):**

**46. In consideration of the anticipated launch of the Certification Scheme in the second quarter of 2023, please tick one of the boxes below in regard to your intentions to certify products made at your own sites in 2023 and 2024.\*** Please tick the option that best applies:

*Guidance: We are asking about your intentions, not commitments, at this stage.*

- Will not seek any product certification in 2023 and/or 2024
- Aim to seek certification of 1–3 products in 2023 and/or 2024
- Aim to seek certification of 4–6 products in 2023 and/or 2024
- Aim to seek certification of 7–10 products in 2023 and/or 2024
- Aim to seek certification of >10 products in 2023 and/or 2024
- We have not thought about our intentions in this regard yet as they relate to 2023 and/or 2024

\* This question was asked to help inform AMRIA's thinking and for AMRIA's internal planning purposes. They do not relate to the activities conducted by companies during the survey timeframe and are not reported on.



## Section 3 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
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		

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 supplies an Alliance member company with an antibiotic API and/or drug product (i.e. formulated product). The scope of the survey is on direct suppliers of API(s) and/or drug product(s). Second and third-tier suppliers are out of scope.

### 47. As of 31 March 2023, how many direct antibiotic manufacturing suppliers do you have?

Note: Respondents with no direct antibiotic manufacturing suppliers (responses of '0') will be directed past related questions to the end of the survey.

### 48. As of 31 March 2023, how many of your company's antibiotic manufacturing direct suppliers have had the expectations of the Common Antibiotic Manufacturing Framework (and/or Standard) conveyed to them by your company?

### 49. How has your company conveyed the expectations of the Common Antibiotic Manufacturing Framework (and/or Standard) to your antibiotic manufacturing suppliers?

Please tick all that apply. If you tick 'other', please clarify in the box below:

- As a requirement of a tender process with suppliers (i.e. as part of tender specifications)
- In a written supply contract
- In verbal communications with suppliers (e.g. phone, meetings)
- Other (please specify in the box below; word limit 250 words):

## Section 3 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

Applicable to	R&D pharmaceutical companies	Generics companies	Biotech/SMEs	Diagnostic companies
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		

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 PNEC targets.*

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

*In the previous 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 Common Antibiotic Manufacturing Framework and the list of PNEC targets. You were asked to submit the number of direct supplier sites, and we asked that you submit anonymised findings from the evaluation of your different direct supplier sites. This year, the survey follows the same approach, which enables us to obtain a more nuanced understanding of diversity and variation in the performance of sites that a single company may engage with and will also help you to provide answers to the questions asked in this survey in a robust way. 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 spreadsheet](#) with the different criteria found in the 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 spreadsheet. This spreadsheet will be used by the research team to analyse the evaluations and will not be shared with the Alliance Secretariat in a way that links your data to your company. Please submit your forms to:*

[AMRIA2023survey@randeurope.org](mailto:AMRIA2023survey@randeurope.org).

*Based on the information you complete in the [Excel spreadsheet](#), the survey questions that follow allow you to submit an aggregate status of your direct supplier sites (i.e. ‘How many of your direct supplier manufacturing sites meet the Common Antibiotic Manufacturing Framework requirements?’).*



**50. As of 31 March 2023, how many of your antibiotic manufacturing direct supplier sites have been assessed by audit against the criteria in the Common Antibiotic Manufacturing Framework in the last five years** (where the assessment has been done through an audit performed in accordance with the requirements of the Framework)? Please write a number (e.g. '3'), or if you do not know, please type 'Unknown' in the box.

*Guidance:*

*The Common Antibiotic Manufacturing Framework requires auditing of manufacturing supplier sites at least every five years to ensure that antibiotics manufacturing facilities (including APIs and formulation) minimise their environmental impact. As part of the program, companies are asked to conduct external site tours/reviews of their manufacturing supplier sites to verify that operating conditions and practices are in place and appropriately followed.*

*As defined in the Common Antibiotic Manufacturing Framework, by review, we mean determining whether a supplier 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 processes (site and exterior) consider all of the items listed in the guidance above, they are considered to be adequate. If the reviews are deficient in one or more of the items listed in the guidance above, they are considered to be inadequate.*

*Note: The number you put into the box below as your answer must be equal to or lower than the overall number of direct supplier sites you reported having in the previous question:*

**51. As of 31 March 2023, among your direct supplier manufacturing sites that have been adequately assessed against the criteria in the Common Antibiotic Manufacturing Framework in the last five years, please provide the following:**

*Guidance:*

*We request that you 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 spreadsheet](#) provided to you for 'direct supplier 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 spreadsheet](#) for 'direct supplier 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 spreadsheet](#) for 'direct supplier sites' must be answered with the drop-down option 'no' or 'do not know'.*

*To assess the extent to which your direct supplier sites meet the requirements of the Common Antibiotic Manufacturing Framework, we encourage you to first complete your evaluation in the [Excel spreadsheet](#) 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. Doing so will enable you to effectively answer the question and fill in the boxes below.*

*Note: The number you put into the box below as your answer must be equal to the overall number of direct supplier sites you previously reported as having been assessed against the criteria in the Common Antibiotic Manufacturing Framework criteria.*

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?

**52.** Looking forward, the Alliance manufacturing members' commitment is to drive the implementation of a new Standard across manufacturing sites. **How many of your direct supplier antibiotic manufacturing sites that either do NOT currently meet or that PARTIALLY meet the requirements of the Common Antibiotic Manufacturing Framework requirements do you anticipate FULLY meeting the requirements of the Standard in the following timeframes** (noting the Standard contains all the key elements of the Framework)?

*Guidance:*

*Please use 31 March 2023 as a starting point.*

*We request that you input an answer for each time frame below. If ALL your supplier sites currently FULLY MEET the requirements, please input N/A in each text box. If you do not know or cannot anticipate the timeframe by which they will fully meet requirements, please type 'we cannot anticipate this/do not know' in the boxes associated with a timeframe.*

*Please only count each site once. As a hypothetical example, if you have eight supplier sites that do not fully currently meet the requirements, you might put five will meet requirements in 0–1 years, a further two 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 direct supplier antibiotic sites that do not fully meet the Common Antibiotic Manufacturing Framework requirements (so either do not meet or meet partially) provided in the previous question. If you expect some or all of your supplier sites to fully meet requirements in a timeframe longer than five years, you can explain this in the 'none of the above' option box.*

*The numbers you put into the boxes below must be equal to or lower than the overall number of sites you reported in the previous questions as either not meeting or partially meeting requirements.*

0–1 years

2–3 years

4–5 years

None of the above (please specify the reason):

**53. As of 31 March 2023, 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(s) and drug product(s), 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, it counts as two 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 three different direct supplier manufacturing sites, then this is counted as three products (again, because three different assessments of PNEC adherence will be performed, one per site).

**54. 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 minimising selective pressure on bacteria in the receiving water body to mutate (and thus minimise the 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](#).

**55. As of 31 March 2023, of the antibiotic products manufactured at your direct supplier sites 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 minimising selective pressure on bacteria in the receiving water body to mutate (and thus minimise the 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](#). Your answer assumes that all the products you report on in your answer below have both been assessed against PNEC targets and meet the targets. The answer should be either equal to or lower to the number provided in the previous question. Please check that this is the case.

**56. 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 2023 as a starting point?**

Guidance:

*As a reminder, 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(s) and drug product(s), 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, it counts as two 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 three different direct supplier manufacturing sites, then this is counted as three products (again, because three 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 bodies for antibiotics developed by the AMR Industry Alliance. These values are aimed at protecting ecological species and minimising selective pressure on bacteria in the receiving water body to mutate (and thus minimise the 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](#).*

*Note: The total number of antibiotic products manufactured at your direct supplier sites that have been assessed against PNEC targets BUT that do NOT currently meet PNEC targets must equal the difference between the number of products assessed against PNEC targets and the number of assessed products that meet PNEC targets. Please check that the sum of the numbers you provide in the boxes below adds up this figure.*

We request that you input an answer for each time frame below:

0–1 years

2–3 years

4–5 years

None of the above (please specify the reason):



**57. What actions did your company take between 1 April 2021 and 31 March 2023 to ensure that your direct antibiotic manufacturing suppliers meet the PNEC targets?** Please tick all that apply:

Guidance:

*Please note that we do not plan to report on this information by company; instead, 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.*

- We provided technical guidance/tool kits to suppliers for performing Mass Balance
- We reviewed the supplier Mass Balance (for ALL compounds)
- We reviewed supplier Mass Balance (for SOME compounds but NOT ALL compounds)
- We reviewed supplier-performed sampling and analysis (for ALL compounds)
- We reviewed supplier-performed sampling and analysis (for SOME but NOT ALL compounds)
- We reviewed/checked that our suppliers took corrective actions post audit if such actions were needed
- Provided funding (beyond the supply contract) for a supplier(s) to do any of the above
- No action was taken
- Other (please specify below; word limit 250 words) :

**58. In the prior question, you noted that between 1 April 2021 and 31 March 2023 your company reviewed/checked that your suppliers took corrective actions post audit, if such actions were needed.** Please tick all that apply:

- The suppliers conducted dry/vacuum cleaning of the production area(s)
- The suppliers collected equipment rinses and treated them separately (not to water water)
- The suppliers added additional wastewater treatment technology (revenue expense)
- The suppliers added additional wastewater treatment technology (capital expense)
- Other supplier corrective actions (please detail below; word limit 250 words):



**59. In consideration of the anticipated launch of the Certification Scheme in the second quarter of 2023 (as related to the [Antibiotic Manufacturing Standard](#) published by the AMR Industry Alliance), we are interested in understanding your company's intent in relation to seeking product certification for products made at your direct supplier sites through the scheme.\*** Please tick the one answer that best applies to your overall intent:

*Guidance:*

- We are asking about your intentions, not commitments, at this stage.
- We seek to ensure that all products made at our direct supplier sites are certified over time.
- We seek to ensure that some but not all the products made at our direct supplier sites are certified over time.
- We will not seek to ensure that the products made at our direct supplier sites are certified over time.
- We have not yet thought about our intentions in relation to certification of products made at our direct supplier sites.

**60. Please provide a brief clarification of your rationale as it relates to your certification intentions for products made at your direct supplier sites based on the answer reported in the prior question\*** (word limit 250 words):

**61. In consideration of the anticipated launch of the Certification Scheme in the second quarter of 2023, please tick one of the boxes below in regards to your intentions to certify products from direct supplier sites in 2023 and 2024.\*** Please tick the option that best applies:

*Guidance:* We are asking about your intentions, not commitments, at this stage.

- Will not seek any product certification in 2023 and/or 2024
- Aim to seek certification of 1–3 products in 2023 and/or 2024
- Aim to seek certification of 4–6 products in 2023 and/or 2024
- Aim to seek certification of 7–10 products in 2023 and/or 2024
- Aim to seek certification of >10 products in 2023 and/or 2024
- We have not thought about our intentions in this regard yet as they relate to 2023 and/or 2024

\* This question was asked to help inform AMRIA's thinking and for AMRIA's internal planning purposes. They do not relate to the activities conducted by companies during the survey timeframe and are not reported on.

# Methods

## SURVEY DESIGN, ADMINISTRATION AND ANALYSIS

The objective of the 2023 AMRIA survey was to assess the progress of AMR Industry Alliance members in tackling AMR. The survey covered Alliance member activities in the timeframe of 1 April 2021 to 31 March 2023. The 2023 survey was adapted from the prior round of the survey conducted in 2021 with an intent of focusing the 2023 survey around a prioritised set of key questions and designing closed-ended style questions to facilitate ease of completion. With input from the AMRIA Steering Committee, RAND Europe reviewed the questions asked in the prior survey round for general relevance and relevance to specific sectors in the Alliance. We also considered the response types of questions and how the data would be analysed and reported, balancing detail of information with the priorities of the Alliance. To the extent possible, we retained original wording of questions retained from prior rounds to allow for comparison, when appropriate, to prior survey round data. We included a few new questions related diversity, equality and inclusion and to understand manufacturing members' intentions related to upcoming certification programmes.

One survey was designed for each of the four sectors: R&D pharmaceutical, biotech/SMEs, diagnostics and generics. The survey was coded in SmartSurvey, and question logic was used to ensure that respondents were asked questions that were relevant to their specific sector.

Potential participants included a representative from each Alliance member company, who was sent an introductory email with the project information sheet and the privacy notice, as well as a link to access the survey. Participants were required to consent electronically via the survey portal prior to initiating the survey. Data was collected between 3 April and 8 May 2023.

Survey data were checked, and some follow-ups with individual member companies were conducted to clarify the data where needed. Descriptive statistics were calculated for all survey questions. Data cleaning and analysis were conducted in R and STATA 18.

## PROFILE OF SURVEY RESPONDENTS

Out of 77 members of AMRIA, a total of 43 completed the survey, yielding an overall response rate of 56%. It is worth noting that the response rate was 100% for three of the four sectors. More specifically, all R&D pharma sector (12 out of 12), generics sector (10 out of 10) and

diagnostics sector (4 out of 4) Alliance member companies and 33% (17 out of 51) of biotech/SME sector members responded to the survey.

Of those who participated in the survey, the most common locations Alliance members reported having AMR-related activities in were Europe (77%, n=33), North and Central America (70%, n=30), and South East Asia (58%, n=25). Alliance members also reported having activities in Africa (42%, n=18), South America (42%, n=18), Western Pacific (42%, n=18), Eastern Mediterranean/Middle East (37%, n=16), and other (2%, n=1).

## CAVEATS AND LIMITATIONS

There are some limitations to the work which should be noted. Though the overall response rate is 56%, the response rate for the biotech/SME sector was lower, at 33%. In addition, there were a relatively small number of diagnostics companies in the Alliance and eligible to be included in the survey (n=4). Given these caveats, some caution should be exercised with interpreting the results at the sector level. In addition, though the membership at the sector level has been relatively stable between the prior and current survey round for three of four sectors (R&D pharmaceuticals, biotech and diagnostics), there have been some more substantial changes in the number and nature of the members, especially for the biotech/SMEs sector. This limits the ability to compare results from the current survey with that from prior rounds for research and science, access and appropriate use sections in particular. We do provide some comparison for the manufacturing pillar of Alliance activity given that the membership of companies in sectors who were eligible to complete this part of the survey (i.e. R&D pharmaceutical and generics sector Alliance members) has been relatively stable across the two survey periods. Finally, data are based on self-report by respondent companies. Though there has been some effort to clean the data and ensure clarity, auditing the data was outside of the scope of the work.





## 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](http://amrindustryalliance.org)**