This document is in a different format to the original used in the tender. The content is identical, but this version has been made compliant with WCAG 2.1 AA accessibility standards.

Annex 3: Award questions and criteria

The response to each question must be a stand-alone response. Unless specifically requested in the question, the response must not:

- cross refer to other questions;
- cross refer to other documents;
- include embedded documents;
- refer or link to additional documents;
- include URL links.

Bidders should note that, unless specifically requested, such information will not be considered when evaluating the response;

The Bidders entire response must not exceed the stated A4 page limit with a minimum font size of Arial 12 with single line spacing. The minimum margins in the response template must not be changed. Any element of a response beyond the stated page limit will be disregarded and not considered in the evaluation.

Note – references to a "literature review" (AMR1 & AMR2 below) means a comprehensive summary of previous research on a topic. The literature review surveys scholarly articles, books, and other sources relevant to a particular area of research. The review should enumerate, describe, summarize, objectively evaluate and clarify this previous research.

AMR1 – Unmet Need

Please describe, with supporting evidence, the degree to which the antimicrobial proposed addresses an unmet need including any specific unmet need in the UK.

Your response

Include each of the Key Components for this section.

To support your responses to Key Components 1 to 4 please also provide:

a. an objective summary of any available UK or EU data relevant to the effectiveness of your antimicrobial and/or its comparators against the pathogen(s) listed in Key Component 1 above, together with a copy of the relevant data, and
b. a literature review of the available evidence, together with the associated references.

To achieve a 'Pass' for this question Bidders must achieve the threshold score specified in the ISFT.

Page limits

The Page Limit for this question (incorporating the response to Key Components 1-4), excluding (a) & (b), is: 20 pages.

The Page Limit for (a) the objective summary, is: 20 pages.

The Page Limit for (b) the literature review, is: 20 pages.

Key component 1

List the pathogens included on the WHO priority pathogen list and their relevant ranking, against which your antimicrobial is active and included within the antimicrobials licensed indications.

Methodology and scoring

Scored. Up to a maximum of 11,250 points.

Scoring criteria

WHO Priority Pathogens: This list is subject to change by the WHO. The pathogen priority will be determined by reference to the prevailing WHO list at the time of the final ISFT submission date.

Points will be awarded using the following criteria for each category of pathogen listed (in response to Key Component 1) that are on the WHO priority pathogen list and included within the antimicrobials licensed indications.

Criteria	Points
First Priority 1 pathogen included within the licensed indications	6000
Second Priority 1 pathogen included within the licensed indications	2500
Third Priority 1 pathogen included within the licensed indications	1250
If licensed indications include one or more Priority 2 pathogens	1000
If licensed indications include one or more Priority 3 pathogens	500

Key component 2

For the Licensed Indications included in Key Component 1 above, please:

- describe the unmet need(s) the antimicrobial addresses; and
- specifically, how and why this is / these are relevant to the UK; and
- Demonstrate the benefit provided by the antimicrobial compared with standard care (e.g. reduced length of stay in ICU or other high-risk settings); and
- provide evidence, if available, to support your rationale**.**

Methodology and scoring

Scored. Up to a maximum of 6000 points.

Scoring criteria

Unmet need by licensed indication.

Points will be awarded using the following criteria for only the highest unmet need ascribed to any of the licensed indication(s) included in your response to key component 1.

Criteria	Points
High unmet need – the antimicrobial licensed indication addresses a disease area of key importance (with a high unmet need in the UK (e.g. resistant gram negative blood stream infections or ventilator associated pneumonia VAP) with significant need for improved outcomes.	6000
Medium – the antimicrobial licensed indication addresses an important disease area of significant concern but available and effective current treatment options and UK outcomes broadly acceptable e.g. gram-positive blood stream infections. A licensed indication that addresses a high international unmet need but not a particular issue in the UK.	4000
Low unmet need – the antimicrobial licensed indication addresses a disease area with adequate current treatment options/outcomes e.g. community acquired pneumonia	1000

See additional information:

https://apps.who.int/iris/bitstream/handle/10665/330420/9789240000193-eng.pdf

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/843129/English_Surveillance_Programme_for_Antimicrobial_Utilisation_and_Resistance_2019.pdf

Key component 3

There are a number of key resistance determinants in the UK relevant to the focus of this project, the 4 Ambler classes of beta-lactamases {including the top 5 carbapenem resistance genotypes (OXA-48, KPC, NDM, IMP, VIM) in addition to extended spectrum beta-lactamase (ESBL)} producers, and the nonmutational mechanisms of multidrug resistant (MDR) Pseudomonas (porin OprD, efflux pump).

Please list the activity, or lack of activity, of your product against the 4 Ambler classes of Beta-lactamases and the non-mutational causes of multidrug resistant (MDR) Pseudomonas (Porin OprD, and efflux pump). In addition, list specific activity, or lack of activity of your product against the top 5 Carbapenemase producing genotypes in the UK (OXA-48, KPC, NDM, IMP, VIM).

Methodology and scoring

Scored. Up to a maximum of 6000 points.

Scoring criteria

Performance against key resistance determinants in the UK.

Points will be awarded using the following criteria.

Criteria	Points
Active against pathogens producing beta lactamases from all 4 Ambler classes and active in the presence of the non-carbapenemase mechanisms causing MDR Pseudomonas (porin OprD and efflux pump) i.e. address 6 or more key resistance determinants	6000
Addresses 3-5 out of the 6 key resistance determinants	4000
Addresses 1 or 2 out of the 6 key resistance determinants	1000
No activity against Ambler class Beta-lactamases or the porin/efflux pump mechanisms of MDR Pseudomonas	0

Key component 4

Describe the severity of the clinical setting for the disease area(s) covered by the Licensed Indication(s).

List the disease areas and their clinical severity, that are included within the antimicrobials Licensed Indications (e.g. community uncomplicated urinary tract infection (UTI); Hospital acquired pneumonia; Bacteraemia in ICU). If the licence is pathogen specific, then list the clinical disease area(s) relevant to the pathogen(s) listed in the licence.

Scores will be allocated based on the health setting (e.g. community, outpatient clinic, renal, transplant unit, oncology/haematology, secondary care ward, ICU) most relevant to the antimicrobial.

Methodology and scoring

Scored. Up to a maximum of 6000 points.

Scoring criteria

Points will be awarded using the following criteria for the highest risk clinical setting applicable to the antimicrobial.

Criteria	Points for yes
High risk settings (ICU, cardiothoracic, renal, haematology/oncology, transplant unit, Neonatal, Cystic Fibrosis)	6000
Non-ICU / Low mortality hospital setting	4000
Primary care / community or long-term care facility	1000

AMR2 – Degree of Novelty

Please describe any novel characteristics of the antimicrobial offered.

Your response

Include each of the Key Components for this section.

To achieve a 'Pass' for this question Bidders must achieve the threshold score specified in the ISFT.

To support your responses to Key Components 1 to 5, please also provide a literature review of the available evidence, together with the associated references.

For the purpose of this procurement, a new chemical class of antibiotic is as defined in the WHO antimicrobial pipeline document which in turn references the Theuretzbacher paper: Theuretzbacher U, Gottwalt S, Beyer P, Butler M, Czaplewski L, Lienhardt C et al. Analysis of the clinical antibacterial and antituberculosis pipeline. Lancet. 2018;18:30513–9.
https://apps.who.int/iris/bitstream/handle/10665/330420/9789240000193-eng.pdf

Page limits

The Page Limit for this question, excluding the literature review is: 20 pages.

The Page Limit for the literature review, is: 20 pages**.**

Methodology and scoring

Scored. Up to a maximum of 9000 points.

Key component 1

Confirmation that the antimicrobial is either a new chemical class of antibiotic; or an adjustment to an existing class;

a. If it is a new chemical class of antibiotic, a description, together with any supporting evidence, of the additional benefits it offers / will offer

b. If it is an adjustment to an existing class, a description, together with supporting evidence, of the additional benefit the adjustment confers compared with existing therapeutic options?

Methodology and scoring

Scored. Up to a maximum of 2000 points.

Scoring criteria

The antimicrobial is a new chemical class of antibiotic (2000 points).

Key component 2

Confirmation of whether the antimicrobial acts on a new pathogen-specific target compared to existing agents in use for the relevant pathogen(s) and a description, together with supporting evidence, of any additional benefits this confers.

Methodology and scoring

Scored. Up to a maximum of 1500 points.

Scoring criteria

The antimicrobial acts on a new pathogen specific target (1500 points).

Key component 3

Confirmation of whether the antimicrobial has a new mechanism of action compared with relevant comparators and a description, together with supporting evidence, of any additional benefits this confers.

Methodology and scoring

Scored. Up to a maximum of 1500 points.

Scoring criteria

The antimicrobial has a new mode of action (1500 points).

Key component 4

Confirmation of whether the antimicrobial bypasses current mechanisms of resistance, or has reduced susceptibility to development of resistance to antimicrobials (& by what mechanism), and a description, together with supporting evidence, of any additional benefits this confers; please describe whether the antimicrobial has any cross resistance with any existing classes of antimicrobials.

Methodology and scoring

Scored. Up to a maximum of 3500 points.

Scoring criteria

Criteria	Points
The antimicrobial has reduced susceptibility to development of resistance compared to existing member of the same class and/or to other relevant antimicrobials	1500
By passes current mechanisms of resistance	1000
No cross resistance to other classes of antimicrobials	1000

Key component 5

Details of any reduced toxicity, or other benefits, associated with the antimicrobial compared with relevant comparators and a description, together with supporting evidence, of any additional benefits this confers; (e.g. Is the drug stable enough for it to be suitable for outpatient intravenous antibiotic regimens).

Methodology and scoring

Scored. Up to a maximum of 500 points.

Scoring criteria

The antimicrobial is a modification of existing chemical class with additional benefits (e.g. dosing, less toxicity, easier route or lower frequency of administration, reduced duration of administration to achieve cure, or enhanced stability lending itself suitable for home intravenous antibiotic regimens; or enhanced entry into the bacterium) (500 points).

AMR3 – Surety of supply

Please describe, with supporting evidence, your proposed supply chain arrangements to comply with the Surety of Supply Minimum Requirements and to ensure your antimicrobial will be available to prescribe and dispense, when and where required in England.

Your response

Your response should include each of the following Key Components:

1. The proposed arrangements to ensure availability of raw ingredients including active pharmaceutical ingredient (APIs);
2. The proposed arrangements to ensure availability of manufacturing sites throughout the supply chain and the associated contingency arrangements;
3. The proposed distribution model within England, including: the total minimum stock, holding points, distribution arrangements, guaranteed delivery times from receipt of order, proposed local stock, etc;
4. Any other arrangement you consider relevant to avoid issues or disruption to the availability of the antimicrobial to the NHS in England under usage consistent with appropriate antimicrobial stewardship;
5. The proposed arrangements to accommodate a 5-fold unexpected increase in demand;

Note:

a. the components listed above are of equal importance,
b. scores will be applied on the basis of the overall response to this question AMR3 – i.e. no sub weightings are applied to the Key Components above.

To achieve a 'Pass' for this question Bidders must achieve the threshold score specified in the ISFT.

Minimum requirements

At any time during the contract, the supplier must:

- Maintain within the supply chain, sufficient capacity to satisfy 30 months of the anticipated demand in England. The supply chain capacity may include a combination of physical stock in England, manufactured product suitable for the UK and API,
- Hold physical stock in England, equivalent to at least 6 months of the anticipated demand in England;

- Maintain supply capability and capacity to replenish stock in the UK within 90 days of order placement;
- provide a five day a week service to deliver to any Purchasing Authority within 24 hours of the order being placed or by the requested delivery date; together with an emergency / out of hours service to deliver at weekends or out of hours, if required;
- guarantee a delivery service level of 95% i.e. 95 out of 100 deliveries are delivered in accordance with the specification to the required location by the required date or within 24 hours of the order being placed.

Page limits

The Page Limit for this question is: 20 pages.

Methodology and scoring

Scored. Up to a maximum of 5000 points.

Criteria	Score
Response / Evidence is sufficient in qualitative terms, convincing and credible such that the Authority has confidence that the antimicrobial will be available to prescribe and dispense, when and where required in England	Confidence 5000
Response / Evidence has only minor gaps, or to a small extent is unconvincing such that the Authority has only minor concerns that the antimicrobial will not be available to prescribe and dispense, when and where required in England	Minor Concerns 3500
Response / Evidence has gaps, or is unconvincing, or lacks credibility, or is irrelevant to the question such that the Authority has concerns that the antimicrobial will not be available to prescribe and dispense, when and where required in England	Concerns 1000
Response / Evidence has major gaps, is unconvincing in many respects, lacks credibility, or largely irrelevant to the question such that the Authority has major concerns that the antimicrobial will not	Major Concerns 0

Criteria	Score
be available to prescribe and dispense, when and where required in England	

AMR4 – Antimicrobial Stewardship

Please confirm and demonstrate, with supporting evidence, your organisations commitment to antimicrobial stewardship and good antimicrobial manufacturing and environmental practice.

Your response

Your response should include each of the following Key Components:

Stewardship

1. To act and behave in a manner consistent with the principles of good antimicrobial stewardship;
2. To delink sales representative remuneration from the quantity of antimicrobial supplied in England;
3. To support education of healthcare professionals regarding appropriate use of your antimicrobial consistent with good antimicrobial stewardship;
4. Not to promote your antimicrobial so as to encourage its inappropriate use over alternatives or that is inconsistent with good antimicrobial stewardship;
   (Note – for the purpose of this procurement, 'education' means the sharing and/or explanation of factual or evidence-based information to support appropriate use of the product in accordance with stewardship guidance or recommendations.)
5. To comply with any antimicrobial stewardship recommendations resulting from the Health Technology Assessment and / or Public Health England;
6. To describe any stewardship arrangements already in place for your antimicrobial and/or propose specific stewardship arrangements you consider appropriate for your antimicrobial;

Manufacturing and environmental practice

7. A signatory to the AMR Industry Alliance Declaration;
8. Demonstrated compliance, via independent assessment, with the AMR Industry Alliance manufacturing standards;
9. Demonstrated compliance, via independent assessment, with good antimicrobial manufacturing practice throughout the supply chain;
10. Demonstrated compliance, via independent assessment, with environmental standards relevant to the manufacture of antimicrobials throughout the supply chain, including compliance with discharge limits at owned and/or supplier manufacturing sites and external wastewater treatment plants;

Note:

a. the 10 Key Components listed above are of equal importance,
b. scores will be applied on the basis of the overall response to both parts (Stewardship and Manufacturing and environmental practice) of this question AMR4 – i.e. no sub weightings are applied to the Key Components above.

The above criteria have been informed by the AMR Benchmark published by the Access to Medicine Foundation and the AMR Industry Alliance.

To achieve a 'Pass' for this question Bidders must achieve the threshold score specified in the ISFT.

Page limits

The Page Limit for this question is: 20 pages.

Methodology and scoring

Scored. Up to a maximum of 5000 points.

Criteria	Score
Response / Evidence is sufficient in qualitative terms, convincing and credible such that the Authority has confidence that the Bidder will comply with antimicrobial stewardship and good antimicrobial manufacturing and environmental practice.	Confidence 5000
Response / Evidence has only minor gaps, or to a small extent is unconvincing such that the Authority has only minor concerns that the Bidder will not comply with antimicrobial stewardship and good antimicrobial manufacturing and environmental practice.	Minor Concerns 3500
Response / Evidence has gaps, or is unconvincing, or lacks credibility, or is irrelevant to the question such that the Authority has concerns that the Bidder will not comply with antimicrobial stewardship and good antimicrobial manufacturing and environmental practice.	Concerns 1000

Criteria	Score
Response / Evidence has major gaps, is unconvincing in many respects, lacks credibility, or largely irrelevant to the question such that the Authority has major concerns that the Bidder will not comply with antimicrobial stewardship and good antimicrobial manufacturing and environmental practice.	Major Concerns 0

AMR5 – Antimicrobial Surveillance

Please confirm your organisations commitment to antimicrobial surveillance and describe your proposed arrangements to demonstrate that commitment.

Your response

Your response should include each of the following Key Components:

1. To support surveillance efforts relating to your antimicrobial in England; (1000 points)
2. To work with NICE and NHS England & NHS Improvement to implement antimicrobial surveillance recommendations in England that may result from the HTA process; (1000 points)
3. To monitor usage and emergence of resistance, wherever your antimicrobial is supplied; (1000 points)
4. To make NICE and NHS England & NHS Improvement aware of any emergence of resistance as soon as it is identified (irrespective of where identified) and to share with NICE and NHS England & NHS Improvement any associated information and data; (1000 points)
5. To provide any additional information or data relating to antimicrobial surveillance reasonably requested by NICE or NHS England & NHS Improvement. (1000 points)

To achieve a 'Pass' for this question, Bidders must commit to each Key Component and achieve the Threshold Score specified in the ISFT

Page limits

The Page Limit for this question is: 10 pages.

Methodology and scoring

Scored. Up to a maximum of 5,000 points.

Criteria	Score
Confirms the organisations commitment to the Key Component and the proposed arrangements to demonstrate that commitment are sufficient in qualitative terms, convincing and credible such that the	Confidence 1000

Criteria	Score
Authority has confidence that the Bidder will meet their commitment to support antimicrobial surveillance.	
Confirms the organisations commitment to the Key Component, however the proposed arrangements to demonstrate that commitment has only minor gaps, or to a small extent is unconvincing such that the Authority has only minor concerns that the Bidder will not comply with their commitment to support antimicrobial surveillance	Minor Concerns 700
Confirms the organisations commitment to the Key Component, however the proposed arrangements to demonstrate that commitment has gaps, or is unconvincing, or lacks credibility, or is irrelevant to the question such that the Authority has concerns that the Bidder will not comply with their commitment to support antimicrobial surveillance.	Concerns 500
Confirms the organisations commitment to the Key Component, however the proposed arrangements to demonstrate that commitment has major gaps, is unconvincing in many respects, lacks credibility, or largely irrelevant to the question such that the Authority has major concerns that the Bidder will not comply with their commitment to support antimicrobial surveillance.	Major Concerns 400
Does not confirm the organisations commitment to the Key Component	No Commitment 0