



**Provision of [a New][an Existing] Antimicrobial to the  
NHS in England via a subscription-based payment  
model**

**Invitation to Participate in Dialogue  
Stage 1**

Tender Reference: [xxxx]

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## 1. Notice to Bidders

- 1.1 This Invitation to Participate in Dialogue (ITPD) document is being made available on the condition that the information contained within it is used solely in connection with the competitive tender process to procure the Requirement (as defined hereinafter) on behalf of NHS England (the Authority) and for no other purpose.
- 1.2 Whilst reasonable care has been taken in preparing the ITPD, neither the Authority nor any of its advisers accepts any liability or responsibility for the adequacy or completeness of any information or opinions stated in this ITPD. No representation or warranty, express or implied, is or will be given by the Authority or any of its representatives, employees, agents or advisers with respect to the ITPD or to any information on which it is based. Any liability for such matters is expressly disclaimed.
- 1.3 In this ITPD document, words such as “anticipates”, “expects”, “intends”, “plans”, “believes” and “will” (and words and terms of similar substance) indicate the Authority's present expectation of future events, which are subject to a number of factors and uncertainties that could cause actual requirements to differ materially from those described.
- 1.4 Neither the issue of this ITPD nor any of the information presented in it should be regarded as a commitment or representation on the part of the Authority (or any other person) to enter into a contractual arrangement. If a Bidder proposes to enter into an agreement with the Authority, it must rely on its own enquiries and on the terms and conditions set out in the agreement(s) (as and when finally executed), subject to the limitations and restrictions specified in it.
- 1.5 In so far as it is compatible with any relevant laws, the Authority reserves the right, without prior notice, to change the basis of, or the procedures for, the competitive process for the award of the contract or to reject any or all Tenders and to terminate discussions involving (directly or indirectly) Bidders at any time. In no circumstances will the Authority incur any liability in respect of the foregoing.

## 2. Summary of the Procurement

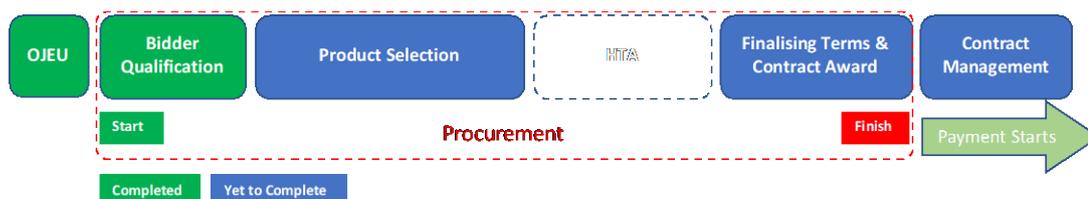
### 2.1 Introduction

- 2.1.1 This document should be read in conjunction with Section 2 and Section 3 of the *Information for Bidders* document provided with the Selection Questionnaire.
- 2.1.2 The Authority is undertaking this procurement in accordance with the Public Contracts Regulations 2015 (as amended) and will use the Competitive Dialogue (CD) award procedure.
- 2.1.3 This ITPD represents the beginning of the first stage of the Competitive Dialogue process. The purpose of the dialogue is to identify the solution(s) and Bidder(s) which can best meet the Authority's Requirements.
- 2.1.4 In summary, the aim of this ITPD stage 1 is to enable the Authority to glean, inter alia, an understanding of the range of Bidders' potential solutions that may be capable of meeting the Requirement together with Bidders' indicative costs proposals and to initiate dialogue with Bidders in relation to the Initial Solutions proffered. Detailed information of the proposed structure of the Competitive Dialogue process leading up to the award of contract is set out in detail in Section 3 of this ITPD.

### 2.2 Overview of the Procurement

- 2.2.1 This Procurement relates to the selection of [a **new**] [an existing] antimicrobial that can best satisfy the Authority's Requirements in the NHS in England and where remuneration for its supply will be via a fixed fee, unrelated to the volume supplied.
- 2.2.2 Subject to receipt of compliant offers and its formal approval processes, the Authority intends to award a single contract for supply of the [new] [existing] antimicrobial that best satisfies the Authority's Requirements.
- 2.2.3 The process for this Procurement includes the following key steps:
- a) Product Selection
  - b) Health Technology Assessment
  - c) Finalising terms and Contract Award

**Figure 1 Summary Process**



## Product Selection

2.2.4 The Authority has specified requirements and an evaluation methodology for determining product selection (*see Section 4 - Award Methodology & Criteria*). The Award Criteria are designed to allow the Authority to identify, in advance of the HTA, the product most likely to address the Requirements of the NHS in England. The product selection process incorporates discussion (dialogue) between the Authority and individual Bidders. The Bidder whose product is selected via this process will be the sole Bidder invited to proceed to the HTA and finalise terms.

## Health Technology Assessment

2.2.5 The Health Technology Assessment (HTA) will aim to estimate the value of the product to the NHS in England. The process will test an experimental, adapted HTA that goes beyond the normal assessment of the health benefit for individual patients by also capturing the additional elements of value to the health system and wider population which are unique to antibiotics. The HTA process will be led by the National Institute for Health and Care Excellence (NICE).

## Finalising Terms & Contract Award

2.2.6 Following completion of the HTA and informed by its outcome, the Authority will finalise contractual terms with the winning Bidder and (subject to necessary approvals) proceed to contract Award.

2.2.7 The supply of the selected antimicrobial(s) shall be in accordance with the terms of the Contract.

2.2.8 It is anticipated that the Contract will commence on 1 April 2022.

## 2.3 Timetable

2.3.1 The indicative timetable for the Competitive Dialogue is set out below. Whilst the Authority does not intend to depart from the timetable, they reserve the right to do so at their sole discretion.

**Table 1 – Procurement Timetable**

<b>Activity</b>	<b>Target Date</b>
<b>Product Selection Stage 1</b> - ITPD issued to selected Bidders (via Atamis)	17/08/2020
Initial Solution submission	07/09/2020
<b>Product Selection Stage 2</b> – Commence Competitive Dialogue	21/09/2020
Competitive Dialogue Closed	30/10/2020
<b>Product Selection Stage 3</b> - Invitation to Submit Final Tender (ISFT)	06/11/2020
Draft ISFT ( <b>Optional at Authority's discretion</b> )	
Final Tender response deadline	20/11/2020
Final Tender Evaluation	18/12/2020
Notify Bidders of the product selected for HTA	Dec 2020
<b>HTA</b>	Jan-Dec 2021
<b>Contract Finalisation, Approvals, Contract Award and Standstill Period</b>	Jan-Mar 2022
<b>Contract Mobilisation / Commencement</b>	April 2022

## 2.4 Clarifications and Submission Date

- 2.4.1 Bidders can raise clarifications on the content of this ITPD and the Requirement generally via the NHS England Atamis E-Tendering Portal and until the deadline specified therein.
- 2.4.2 Bidders must submit their response to the ITPD via the NHS England Atamis E-Tendering Portal no later than deadline specified therein.
- 2.4.3 Please note that Bidder clarifications and / or Tender submissions received after the closing deadlines may be rejected.

## 2.5 Procurement Documents

- 2.5.1 Documents and information related to the Procurement are located in the *Documents* section of the NHS England Atamis E-Tendering Portal.
- 2.5.2 The Procurement Documents and information may be updated from time to time.
- 2.5.3 The Bidder's Authorised Representative will be notified via the Atamis portal if documents are added or updated.
- 2.5.4 Any difficulties or problems with access to the NHS England Atamis E-Tendering Portal or any of the documents or information contained therein should be reported by contacting the Atamis Helpdesk.

## 3. The Competitive Dialogue Process

### 3.1 Introduction

- 3.1.1 The Requirement is being procured under the Competitive Dialogue process (**Dialogue**). The Dialogue is a process during which Bidders discuss with the Authority their solution and the contractual documents, with a view to reaching a solution and a set of contract documentation which can form the basis of a final tender. Post tender, further negotiation is not permitted by law, and so any changes which take place may only be of a clarificatory nature and may not affect the key commercial aspects of the Final Tender.
- 3.1.2 It is therefore important for Bidders to note that they **must** raise all significant points which they wish to raise during the Dialogue phase.
- 3.1.3 The Authority will consider incorporating proposals for change which are based on, for example, improving workability or value for money, but does not guarantee to do so. The intention is to work towards a single common set of contract documents (so far as possible) upon which the Final Tenders are to be based.
- 3.1.4 The aim of this structure is to enable consistency and fairness in scoring the Bidders' Final Tenders, and also to achieve efficiency in the Dialogue process and save both the Authority and the Bidders from incurring excessive costs.

### 3.2 ITPD Stage 1 – Initial Solutions

- 3.2.1 This ITPD represents the first stage in the Competitive Dialogue process.
- 3.2.2 The objective of ITPD Stage 1 is to (i) enable the Authority to gain a better understanding as to the range, nature and scope of Bidders' potential solutions to meet the Authority's Requirements including (but not limited to) the key clinical, technical, commercial, legal and financial issues that arise in relation to the Requirement; and (ii) initiate dialogue with Bidders on their proposed Initial Solutions.
- 3.2.3 Initial Solutions will form the basis of dialogue with each Bidder – see ITPD Stage 2 below.
- 3.2.4 Bidders will have the opportunity to engage with the Authority via the Atamis portal to raise any clarifications in advance of submitting their Initial Solutions
- 3.2.5 **NOTE** –Bidders' Initial Solutions will not be scored, and there will not be any down selection (short listing) at this ITPD stage 1. However, any Initial Solution which does not include the Deliverables in 25 and/or meet the Authority's minimum requirements

(set out in Annex 1 (Authority's Requirements) may be deemed non-compliant and subsequently disqualified.

3.2.6 **NOTE FURTHER** – Although there will be no down-selection at this stage, the Authority may, at its discretion, give feedback to Bidders in respect of their Initial Solutions. Where any Bidder appears to have significant deficiencies in their solution which might make their solution unacceptable at Final Tender stage unless addressed, the Authority reserves the right to inform that Bidder of the deficiency / gap and offer that Bidder the option of withdrawing. The Bidder is not bound to do so and there will be no prejudice to the Bidder if it decides to continue – this is intended purely as an honest indication of the position at an early stage so that Bidders who are trailing may, at their discretion, take the option of saving costs and withdrawing.

### 3.3 ITPD Stage 2 – Detailed Dialogue

3.3.1 The Authority will conduct detailed dialogue meetings with each of the participating Bidders who have responded to ITPD Stage 1 for the purpose of discussing their respective proposals, narrowing down potential issues and refining the Authority Requirements with the aim of (i) identifying and defining the means of achieving the best solution to meet the Authority's Requirements and (ii) developing the Contract.

3.3.2 Bidders need to ensure they have appropriate legal, technical and financial support personnel available during this stage of the procurement and maintain continuity of these personnel throughout the process.

3.3.3 The dialogue process will include a series of meetings with each Bidder to discuss particular aspects of the Requirement / ITPD documentation to address, inter alia, the following:

- a) the characteristics of the Bidders offered product;
- b) the payment mechanism, invoice price and performance criteria;
- c) the commercial terms;
- d) the supply, stewardship and surveillance requirements; and
- e) contract monitoring and reporting.

3.3.4 A detailed dialogue plan and Rules of Engagement will be provided to each Bidder in due course

3.3.5 The Authority reserves the right at any time not to continue the detailed dialogue Stage with any of the Bidders, to extend or shorten the detailed dialogue Stage including the number of meetings / rounds of dialogue to be held.

- 3.3.6 At this juncture it is anticipated that there will be a minimum of 4 rounds of dialogue meetings with each Bidder. The duration of each dialogue meeting will be between 3 to 4 hours.
- 3.3.7 The dialogue process may also include the submission of further written proposals, presentations, meetings and interviews.
- 3.3.8 In preparation for the Final Tender Stage, the Authority will issue a revised Contract. Changes incorporated into the revised Contract from the detailed dialogue Stage will be implemented across the board for all Bidders; in other words there will be a standard Contract so far as possible.
- 3.3.9 Bidders will get one further opportunity to respond to the Authority, with points which must be either related to points they have raised before, or arise from drafting changes, or are minor typos/gap filling. Entirely new points (unless they result from the revised drafting) will not be discussed at this stage.
- 3.3.10 The Authority will consider any points raised and may (at its discretion) elect to have further meetings to discuss these with the Bidders.

#### **3.4 Draft Invitation to Submit Final Tender (“Draft ISFT”) - Stage 3(a) (optional)**

- 3.4.1 The Authority may, at its discretion, undertake a Draft ISFT stage. This stage, if undertaken, is intended to enable Bidders to prepare and submit a draft final tender response setting out, inter alia, the solutions which have developed through the dialogue process to date. It is also intended to provide an indication of the Authority's expected position regarding the evaluation criteria and scoring methodology at the invitation to submit final tender (ISFT) stage (although the Authority reserves the right to change its position at the ISFT stage).

#### **3.5 Invitation to Submit Final Tender (“ISFT”) - Stage 3(b)**

- 3.5.1 Once the Authority is satisfied that it has identified the solution or solutions which it considers will meet its Requirements, it will declare the dialogue concluded and invite Final Tenders from those Bidders still in the competition.
- 3.5.2 In response Bidders will submit their Final Tenders. The Final Tenders must be based on the solution(s) identified at the conclusion of the Dialogue and should meet all the Authority Requirements.
- 3.5.3 Bidders will have one (1) opportunity only to respond to the Authority with their Final Tender, which must include all of the following Deliverables:

- a) A completed Clinical Response Template ([Annex 4](#)) responding to each of the clinical questions contained therein;
- b) A completed Non-Clinical Response Template ([Annex 5](#)) responding to each of the non-clinical questions contained therein;
- c) A completed Financial Response Template ([Annex 6](#)) specifying a Supplier Maximum Contract Value less than or equal to the NHSE&I Maximum Contract Value;
- d) Confirmation of their acceptance of the Contract
- e) A Confidentiality Undertaking ([Annex 9](#)); and
- f) A FOI Declaration ([Annex 10](#)).

3.5.4 The Authority may at its discretion seek to “clarify, specify and optimise” elements of any Bidders' Final Tender, provided this does not involve changes to the basic features of the Final Tender. It must be stressed that the Authority's may not, and will not, enter into any negotiation of any material feature or key contract term of the Final Tenders post-tender. Any activity which leads to changes to a Final Tender will not be allowed to change a material feature of a Final Tender, key contract term or distort competition.

3.5.5 The Authority reserves the right at any time not to commence or continue the ISFT Stage with Bidders.

3.5.6 Following the submission of Final Tenders, the Authority will undertake an evaluation and selection process to identify the Bidder (the “Winning Bidder”) who provides the most economically advantageous tender, to whom the Authority's is minded to award the contract.

3.5.7 The Authority will notify the Winning Bidder and the other Bidders of the outcome. This does not yet constitute the award of a contract or a promise or decision to award a contract. The Winning Bidder will then proceed to HTA.

## **3.6 Health Technology Assessment (HTA) Process**

3.6.1 The purpose of the HTA process is to estimate the value of the product to the NHS in England.

3.6.2 The process will test an experimental, adapted HTA that goes beyond the normal assessment of the health benefit for individual patients by also capturing the additional elements of value to the health system and wider population which are unique to antibiotics.

3.6.3 The HTA process will be run by the National Institute for Health and Care Excellence (NICE).

3.6.4 Further details of the HTA process are provided in Annex 7.

3.6.5 It is anticipated that the HTA recommendations will be available to both NHSE&I and the Winning Bidder.

### 3.7 Finalising Terms & Contract Documents

3.7.1 Following selection of the Winning Bidder and post the HTA process there may be further activity between the Authority and the Winning Bidder to (i) "confirm financial commitments or other terms contained in the Final Tender" and (ii) to take account of the outcome of the HTA; provided, again, that there are no material changes to the Final Tender and that this does not risk distorting competition or causing discrimination.

3.7.2 It is anticipated that, informed by the outcome of the HTA, this stage will encompass and conclude:

- a) stewardship guidance to the NHS in England regarding the selected antimicrobial;
- b) finalising the supply, stewardship and/or surveillance requirements to reflect the product specific HTA recommendations;
- c) finalising the contract performance criteria (KPIs) to reflect the product specific HTA recommendations.
- d) agreement of the annual Contract Value to be paid to the winning Bidder, **provided that** the annual Contract Value is equal to or less than the lesser of the NHSE&I Maximum Contract Value or the Bidder Maximum Contract Value

3.7.3 During this period some or all aspects of the financial information provided at SQ stage may also be confirmed or re-checked at this stage. This will not be re-scored, and the process is purely to ascertain that the information given at SQ stage is still correct and that there have been no significant adverse changes.

3.7.4 Once all matters are satisfactorily completed, the Authority will make its decision whether to award the contract to the Winning Bidder.

### **3.8 Standstill Period**

- 3.8.1 Once the Authority has reached a decision in respect of contract award it will notify all Bidders of that decision and provide a standstill period of 10 calendar days before entering into a contract (the “Contract”) with the Winning Bidder.
- 3.8.2 Certain information regarding the scores achieved by Bidders and the score of the winning Bidder will be made available to individual Bidders as required by law. Further debrief information may be requested and this procedure will be clarified to Bidders later in the process.

### **3.9 Approvals**

- 3.9.1 The award of contract is subject to the formal approval processes of the Authority. Until all necessary approvals are obtained and the standstill period (referred to above) has elapsed, the Contract will not be entered into and will not become contractually binding.

## **4. Award Methodology & Criteria**

### **4.1 Introduction**

- 4.1.1 Any contract awarded as a result of this procurement will be on the basis of the offer which is most economically advantageous to the Authority.
- 4.1.2 Bidders' Tender submissions will be evaluated by the Authority applying the evaluation criteria set out in this Section 4 and Annex 3.
- 4.1.3 NOTE - although the high-level criteria will remain consistent throughout the procurement process, the relative weightings of the underlying sub-criteria assigned to each of the evaluation criteria may, at the Authority's sole discretion, be varied during the course of the procurement process.
- 4.1.4 Bidders will be notified, sufficiently in advance of any Tender submission that is to be scored or evaluated, of the relative weightings of the underlying sub-criteria, so that Bidders can take the same into account when preparing their Tender responses.
- 4.1.5 IMPORTANT - Bidders' Initial Solutions submitted in response to this ITPD will NOT be scored or evaluated for the purposes of down selection (or otherwise) at this ITPD stage (see Section 3 of this ITPD for further details).

### **4.2 Award Methodology**

- 4.2.1 The award criteria are grouped into three themes:

- a) Clinical (quality);
- b) Non-clinical (quality); and
- c) Financial (cost).

4.2.2 The award methodology selects the product to progress to HTA and contract award, primarily based upon the quality (clinical and non-clinical) criteria.

4.2.3 Key steps in the award methodology include:

- a) Bidders must achieve a threshold score for the clinical and non-clinical criteria, otherwise they are excluded.
- b) Bidders that achieve the threshold score for the clinical and non-clinical criteria are ranked based upon their overall score i.e. their combined clinical, non-clinical and cost criteria scores (highest score = ranked #1).
- c) The Bidder ranked #1 i.e. that satisfies the threshold clinical and non-clinical criteria and that achieves the highest overall score, wins.
- d) If no Bidder achieves the initial threshold score for the clinical and non-clinical criteria, then the Authority may reduce the threshold in accordance with paragraph 4.5 below until one or more Bidders satisfy the revised threshold.

*Figure 2 Award Methodology*



- e) NHSE&I have established a maximum annual contract value, (the **NHSE&I Maximum Contract Value**) of £10m (Ten Million Pounds) excluding VAT for this project. This is the maximum fee that NHSE&I is prepared to pay per annum for supply of an antimicrobial via a fixed fee payment model over the contract term. .
- f) As part of their submission, Bidders may offer a maximum contract value lower than the NHSE&I Maximum Contract Value (the **Bidder Maximum Contract Value**).
- g) In the award methodology, the contract value used for each Bidder is the lesser of the NHSE&I Maximum Contract Value and the Bidder Maximum Contract Value.

## Example Scenarios:

**Example 1:** Three Bidders are invited to dialogue. Of the three Bidders, two Bidders do not achieve the initial threshold required for clinical and non-clinical scores and are therefore eliminated. Only one Bidder is left who is selected to proceed to HTA. In this example, cost comparison does not influence the outcome.

**Example 2:** Three Bidders are invited to dialogue. Of the three Bidders, one Bidder does not achieve the initial threshold required for clinical and non-clinical scores and is therefore eliminated. The other two Bidders score the same for the clinical and non-clinical criteria. The overall score determines who wins. In this example, cost determines which of the two (clinically and non-clinically equivalent) offers is selected to proceed to HTA.

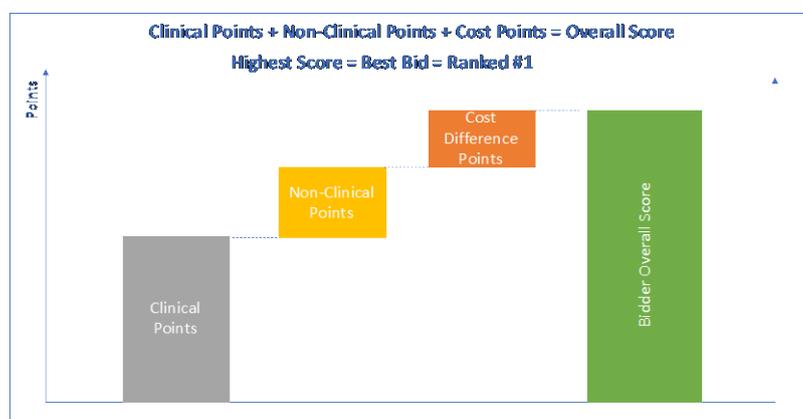
**Example 3:** Three Bidders are invited to dialogue. All three Bidders achieve the initial threshold required for clinical and non-clinical scores; however, they all score differently and have offered different maximum contract values. The overall score determines who wins. In this example, cost contributes to the decision of which offer provides the best combination of quality (clinical & non-clinical) and cost.

**Example 4:** Three Bidders are invited to dialogue. None of the Bidders achieve the initial threshold required for clinical and non-clinical scores. The Authority elects to lower the threshold to the next level (see paragraph 4.5 below). Examples 1, 2 and 3 set out some of the potential scenarios that may arise, dependent upon how many Bidders achieve the clinical and non-clinical scores for the revised threshold.

### 4.3 Combining Clinical, Non-Clinical & Cost Criteria

4.3.1 The methodology to combine the clinical and non-clinical elements of the assessment with cost is illustrated in Figure 3 below.

**Figure 3 Overall Score**



- 4.3.2 In order to combine the three elements, any difference between the NHSE&I Maximum Contract Value and the Bidder Maximum Contract Value is converted into points.
- 4.3.3 The cost difference is converted to points using a conversion rate of £1m = 2,000 points.
- 4.3.4 The points awarded for any cost difference is then added to the clinical and non-clinical points to derive the Bidders Overall Score.
- 4.3.5 The supplier with the highest Overall Score is selected to proceed to HTA, finalising terms, and contract award and implementation.

#### **4.4 Award Criteria**

- 4.4.1 The award criteria are set out in Annex 3.
- 4.4.2 The award criteria are primarily scored criteria where the Bidder provides a written response to a set of questions which are evaluated by a panel of experts in accordance with the scoring methodology and criteria.
- 4.4.3 The clinical themed criteria seek to assess:
- a) The number of WHO priority pathogens included in the licensed indications;
  - b) The degree to which the proposed antimicrobial satisfies a high unmet need in the UK;
  - c) Performance of the antimicrobial against key resistance determinants in the UK
  - d) The clinical severity of the disease area(s) covered by the antimicrobial; and
  - e) The degree to which the proposed antimicrobial is novel;
- 4.4.4 The non-clinical themed criteria seek to confirm commitment to and/or assess:
- a) Surety of supply;
  - b) Antimicrobial stewardship; and
  - c) Antimicrobial surveillance.
- 4.4.5 The financial criteria will determine the annual fee that the supplier will supply their antimicrobial in accordance with the contract, being the lower of:
- a) NHSE&I Maximum Contract Value; or
  - b) The Bidder Maximum Contract Value; or

- c) The value fee agreed between the parties following completion of the HTA process.

4.4.6 NOTE - The contract value agreed following the HTA cannot exceed the lower of the NHSE&I Maximum Contract Value and the Bidder Maximum Contract Value.

4.4.7 Table 2 summarises the recommended points per clinical (AMR1 & AMR2) and non-clinical (AMR3 to AMR5) criteria.

**Table 2 – Points per Criterion**

**AMR1 – Key component 1, WHO Priority Pathogens**

Criteria	Points
1st Priority 1	6,000
2nd Priority 1	2,500
3 <sup>rd</sup> Priority 1	1,250
Any / All Priority 2	1,000
Any / All Priority 3	500

**AMR1 – Key component 2, unmet need**

Criteria	Points
High	6,000
Medium	4,000
Low	1,000

**AMR1 – Key component 3, key resistance determinants**

Criteria	Points
High	6,000
Medium	4,000
Low	1,000
None	0

**AMR1 – Key component 4, disease setting**

Criteria	Points
High	6,000
Medium	4,000
PC	1,000

**AMR2 – Key components 1 to 5**

Criteria	Points
----------	--------

New Class	2,000
New Pathogen Target	1,500
New Mode of Action	1,500
Reduced susceptibility	1,500
No cross resistance	1,000
Additional Benefits	500

### AMR3 – surety of supply

Criteria	Points
Confidence	5,000
Minor Concerns	3,500
Concerns	1,000
Major Concerns	0

### AMR4 – antimicrobial stewardship

Criteria	Points
Confidence	5,000
Minor Concerns	3,500
Concerns	1,000
Major Concerns	0

### AMR5 – antimicrobial surveillance

Criteria	Points
Pass	3,500 or more
Fail	Less than 3,500

#### Example Scenarios (non-exhaustive) for AMR1 KC1:

1. An antimicrobial that is active against one Priority 1 pathogen will score 6000 points;
2. An antimicrobial that is active against two Priority 1 pathogens will score 8500 points (6000 + 2500);
3. An antimicrobial that is active against three Priority 2 pathogens will score 1000 points;
4. An antimicrobial that is active against two Priority 1 and two Priority 2 pathogens will score 9500 points (6000 + 2500 + 1000);

## 4.5 Clinical & Non-Clinical Threshold Scores

- 4.5.1 Bidders must achieve a threshold score for the clinical and non-clinical criteria, otherwise they will be excluded from the procurement process.

- 4.5.2 The initial threshold scores required to pass the clinical and non-clinical criteria are included in [Table 3](#)
- 4.5.3 If no Bidder achieves the initial threshold score for the clinical and non-clinical criteria at the Final Tender stage, then the Authority may reduce the thresholds in accordance with Table 3 until at least one Bidder satisfies the revised threshold. The Authority will then apply the revised threshold.

**Table 3 – Clinical & Non-Clinical Threshold Scores**

	<b>Clinical Score Threshold</b>	<b>Non-Clinical Score Threshold</b>
Initial Threshold	Greater than or equal to 24,200 points (c67% of the Maximum Score)	Greater than or equal to 3,500 points for each of AMR3 & AMR4 and 3,000 points for AMR5
Revised Threshold 1	Greater than or equal to 21,800 points (c60%)	Average of AMR3, AMR4 & AMR5 is greater than or equal to 3,000 points
Revised Threshold 2	Greater than or equal to 19,600 points (c54%)	
Revised Threshold 3	Greater than or equal to 18,100 points (c50%)	
Revised Threshold 4	Less than 18,100 points	

- 4.5.4 If no Bidder achieves the threshold score for the clinical and non-clinical criteria, then the threshold mechanism enables the Authority to reduce the threshold, rather than having to abandon the procurement. However, the Authority may, at its sole discretion, elect to abandon the procurement if it considers that once the threshold has been reduced the offered product(s) provide insufficient value to the NHS in England.

## 4.6 Contractual Compliance

- 4.6.1 Bidders should note that at **Final Tender** stage (at the Authority's discretion) contractual compliance will be evaluated on a **Pass/Fail** basis; save where the Authority considers at its sole discretion that certain terms are inconsistent or redundant, the Contract will be non-negotiable. Accordingly, Bidders must confirm their acceptance of the Contract at Final Tender stage to register a Pass. Therefore, it is important for Bidders to raise issues with the Contract (that are open to Bidder comment) during this stage so that they can be dealt with in the Dialogue process.

## 5. Financial

### 5.1 Payment model

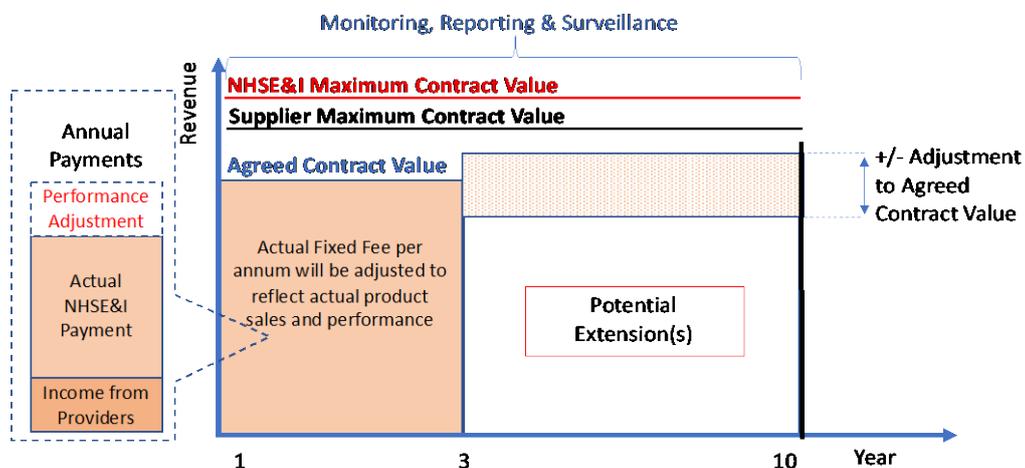
- 5.1.1 This section describes how the NHS will reimburse the Bidder for supply of the antimicrobial in accordance with the Contract via a fixed fee payment model. The payment model includes:
- a) The fixed fee to be paid for supply of the selected antimicrobial in accordance with the terms of the supply contract. (The fixed fee will be determined by the procurement process, informed by the valuation provided by the NICE HTA);
  - b) How and when the fixed fee will be paid;
  - c) How payment for the antimicrobial by provider organisations (e.g. NHS Hospitals) will be handled to maintain separation between the fee paid and quantity supplied;
  - d) The performance requirements that determine the proportion of the fixed fee actually paid;
- 5.1.2 The payment model incorporates a subscription-type contract value (fixed fee) with a performance component, whereby payment of the contract value is not linked to the volume of antimicrobials supplied, however payment of the contract value is contingent upon the Bidder satisfying specified performance (e.g. surety of supply, stewardship and surveillance) requirements.
- 5.1.3 The annual contract value to be paid will be agreed between NHSE&I and the Bidder during the Contract Finalisation stage and will be informed by the outcome of the NICE HTA.
- 5.1.4 **NOTE** however, for this project (to test the HTA process and payment model), irrespective of the HTA valuation, the maximum contract value will be no more than the NHSE&I Maximum Contract Value, or the Bidder Maximum Contract Value offered during the procurement, if lower.
- 5.1.5 Whilst the Authority considers that a fully delinked model is the most appropriate approach, the Authority also recognises that the contract should include a mechanism to limit supplier risk in the event of a truly exceptional increase in demand that could not reasonably have been foreseen. However, the Authority requires that such a mechanism does not materially dilute the delinked nature of the contract. The Authority has included a 'commercial principle' placeholder in the contract to enable further discussion of this topic during dialogue.

## 5.2 The NHSE&I Maximum Contract Value is £10m excluding VAT

- 5.2.1 The maximum contract value will be the maximum income a Bidder will receive in any contract year.
- 5.2.2 The Agreed Contract Value will not be adjusted for inflation during. If the contract is extended beyond the initial term, any adjustments will be determined as part of the contract extension discussions, subject always to any revised maximum contract value being no more than the NHSE&I Maximum Contract Value, or the Bidder Maximum Contract Value offered during the procurement, if lower.
- 5.2.3 The performance requirements include:
- a) Surety of supply;
  - b) Antimicrobial stewardship commitments;
  - c) Compliance with monitoring & reporting requirements;
  - d) Provision of information to support antimicrobial surveillance; and
  - e) Manufacturing & environmental commitments
- 5.2.4 The supplier's performance against the performance requirements will determine what proportion of the maximum contract value is actually paid (the Adjusted Contract Value).
- 5.2.5 There will be no minimum Adjusted Contract Value and the payment for a quarter will be zero if the performance falls below a minimum threshold of performance for that quarter.
- 5.2.6 In addition, in order to ensure the income received is delinked from the amount of product supplied, the adjusted contract value will be reduced by a sum equal (net of VAT) to the value of product purchased by NHS care providers.
- 5.2.7 NHS care providers will purchase the antimicrobial via normal distribution routes at a nationally agreed nominal Invoice Price, with the price being set to encourage appropriate use of the antimicrobial (i.e. the Invoice Price should not be so high as to discourage appropriate use but also not so low as to encourage inappropriate use).
- 5.2.8 During the term of the contract, NHSE&I may undertake a review of the contract:
- a) in the event of the supplier significantly or repeatedly underperforms against the performance requirements; or
  - b) if NICE identify that there has been a material change to the assumptions used within the HTA or a material change to the unmet need addressed by the product.

- 5.2.9 The review may result in adjustments to the contract including to the performance criteria and Maximum Contract Value, subject always to any revised maximum contract value not exceeding the NHSE&I Maximum Contract Value, or the Bidder Maximum Contract Value offered during the procurement, if lower.
- 5.2.10 Adjustments to the contract that result from the review shall be agreed between the Authority and the supplier.
- 5.2.11 The initial contract term will be three (3) years with an option to extend the contract by mutual agreement for a period or periods up to the lesser of (i) the patent expiry or (ii) a maximum of seven (7) years i.e. a maximum total contract length of ten (10) years.
- 5.2.12 If the contract is extended, the annual fee for any extension cannot exceed the NHSE&I Maximum Contract Value, or the Bidder Maximum Contract Value offered during the procurement, if lower. To do otherwise would undermine the basis of the award decision.
- 5.2.13 Either party may terminate the Contract in accordance with, and subject to, its provisions.

**Figure 4 Payment Model**



### 5.3 Payments

- 5.3.1 The Agreed Contract Value, adjusted for performance and NHS care provider purchases, will be paid in quarterly instalments in arrears.
- 5.3.2 Each quarter:

$$\text{Payment} = \text{Adjusted Contract Value for the previous quarter, less NHS Care Provider Purchases for the previous quarter}$$

Where: Adjusted Contract Value for the previous quarter = 25% of the Agreed Contract Value for the contract year less the value of any accrued Service Credits not previously applied.

5.3.3 Table 4 below provides the anticipated timing of performance reviews and payments for each contract quarter.

**Table 4 – Timing of Performance Reviews & Payments (example)**

Contract quarter is April to June.

Month	July	August	September
Performance Reporting (for Contract Quarter)	X		
Performance Review (for Contract Quarter)		X	
Payment (for Contract Quarter)			X

5.3.4 Performance components that are measured less than once per quarter (e.g. if they are assessed annually), will be included in the first review after the performance information is available.

5.3.5 Similarly, Service Credits may be applied to the next and subsequent quarterly payments such that the payments made to the supplier equals the sum that should have been paid to the supplier if the performance information referred to in 5.2.3 above had been available at the end of each quarter.

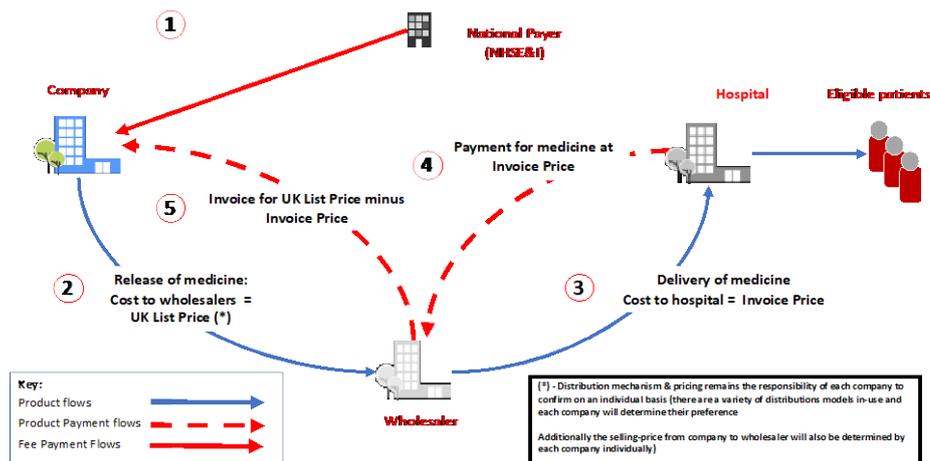
## 5.4 Payment & Supply Flows

5.4.1 NHSE&I pays the supplier the agreed fee in quarterly instalments, adjusted for performance and minus any adjustments for product supplied to NHS care providers;

5.4.2 The supplier provides the product to the NHS care provider at the Invoice Price (via a wholesaler if that is their current / preferred delivery model);

5.4.3 The NHS care provider reimburses the supplier (if needed via a wholesaler) at the Invoice Price;

**Figure 5 Product and Payment Flows**



## 5.5 Invoice Price

- 5.5.1 A national list price will be maintained for the purposes of international reference pricing.
- 5.5.2 A confidential Invoice Price will be provisionally agreed with each Bidder as part of the dialogue process. The final Invoice Price will be agreed during contract finalisation, informed by the outcome of the HTA.
- 5.5.3 All NHS care providers will purchase the product at the agreed Invoice Price.
- 5.5.4 The Invoice Price agreed should:
- be accessible for NHS care providers;
  - be set to encourage appropriate usage (i.e. not be too high so it deters appropriate usage and not too low, so it encourages inappropriate usage);
  - reflect the price or price range of appropriate comparators; and
  - be informed by the price of comparator products referenced in the HTA process.
- 5.5.5 The Invoice Price may be discussed during dialogue to agree principles about how the Invoice Price should be set. However, it is anticipated that the Invoice Price will be agreed between the supplier and the Authority during contract finalisation and that the Invoice Price agreed will be informed by the outcome of the HTA, particularly:
- The pricing of comparator products referenced in the HTA;
  - The pricing of alternative products; and
  - The HTA recommendations about how the product should be used to maximise its value to the NHS in England;

- 5.5.6 If the product is to be used in Secondary Care, then it is anticipated that the product will be purchased by hospitals at the Invoice Price and supplied via normal supply channels;
- 5.5.7 If the product is to be used in Primary Care, then it is anticipated that the product will be purchased by community pharmacies at the List or Tariff Price and supplied via normal supply channels. If used in Primary Care, then as per the process adopted in Secondary Care, the cost of purchases in Primary Care will be deducted from the Fixed Fee;
- 5.5.8 It is anticipated that the contract between the Supplier and the Authority will set out the pricing and purchasing arrangements for Primary and Secondary Care as necessary;
- 5.5.9 This mechanism accommodates different prices for the selected products whilst ensuring the Authority only pays the Agreed Contract Value.
- 5.5.10 Suppliers can utilise their existing supply chain capabilities to supply to NHS care providers at the agreed Invoice Price.

## **5.6 Monitoring Actual Usage**

- 5.6.1 The Supplier shall provide to the Authority on a monthly basis, a report setting out the quantity of antimicrobial delivered to each Purchasing Authority and the delivery date. The Supplier shall provide other information and or evidence of delivery as reasonably requested by the Authority.
- 5.6.2 The Authority shall provide to the Supplier on a monthly basis, a report setting out the quantity of antimicrobial dispensed in secondary care (e.g. via Blueteq data) and primary care (via NHS BSA data);
- 5.6.3 The value of NHS care provider purchases will be calculated based upon the Supplier report, provided this is substantiated by the dispensing data collated by the Authority.
- 5.6.4 Disputes (if any) regarding the value of NHS care provider purchases, shall be resolved in accordance with the dispute resolution procedure set out in the Contract.

## **5.7 Determining the Agreed Contract Value**

- 5.7.1 The Agreed Contract Value will be finalised with the winning Bidder following completion of the HTA.
- 5.7.2 The final terms will be informed by the outcome of the HTA.

5.7.3 The Agreed Contract Value will not exceed the NHSE&I Maximum Contract Value or the Bidder Maximum Contract Value, if lower.

## 5.8 Determining the Adjusted Contract Value

5.8.1 The Adjusted Contract Value is equal to the Agreed Contract Value less the value of any Service Credits.

## 5.9 Performance Framework

5.9.1 Details of the performance requirements (Service Levels and Service Credits) are set out in Schedule 1 Clause 32 and Schedule 10 of the Contract. The performance requirements include:

- a) Surety of supply;
- b) Antimicrobial stewardship commitments;
- c) Compliance with monitoring & reporting requirements;
- d) Provision of information to support antimicrobial surveillance; and
- e) Manufacturing & environmental commitments

5.9.2 Table 5 - Key Service Levels.

	Service Level	Green Level	Amber Level	Red Level
1	API inventory to accommodate at least X months UK demand	$X \geq 24$	$24 > X \geq 18$	$18 > X$
2	Maintain X months forecasted inventory physically in the UK	$X \geq 6$	$6 > X \geq 4$	$4 > X$
3	Maintain a replenishment lead time of X months	$X \leq 2$	$2 < X \leq 4$	$4 < X$
4	Maintain delivery service level of X%	$X \geq 95$	$95 > X \geq 90$	$90 > X$
5	Failure to comply with X stewardship commitments	$X = 0$	$X = 1$	$X \geq 2$
6	Failure to comply with X manufacturing or environmental commitments	$X = 0$	$X = 1$	$X \geq 2$
7	Failure to comply with X surveillance commitment	$X = 0$	$X = 1$	$X \geq 2$
8	Monthly report within X days of report deadline	$0 < X \leq 10$	$10 < X < 30$	$30 \leq X$
9	Quarterly report within X days of report deadline	$0 < X \leq 10$	$10 < X < 20$	$20 \leq X$

## 5.10 Changes to the Licensed Indications

5.10.1 If, during the contract period, the licensed indication changes such that the indications considered in the HTA are no longer valid, the authority may terminate the contract. If the licensed indication is extended but the indications considered in the HTA are still valid, the contract should remain in force.

## 6. Legal and Contractual

### 6.1 Contract Structure

6.1.1 NHS England will enter into an NHS Standard Contract with the appointed Supplier for provision of the antimicrobial.

6.1.2 The Contract will contain (amongst other 'local' terms):

- a) bespoke payment provisions;
- b) obligations on the Supplier to deliver the antimicrobial included in their Final Offer;
- c) obligations on the Supplier to comply with the performance requirements; and
- d) obligations on the Supplier to comply with the specification.

### 6.2 Form of Contract

6.2.1 The Contract will be signed by the Supplier and NHS England.

6.2.2 The draft Contract (subject to inclusion of schedules that are subject to the outcome of dialogue) is included within the Procurement Documents at Annex 8.

6.2.3 The draft Contract is the NHS Standard Contract for the Supply of Goods and the Provision of Services (Contract version).

6.2.4 Bidders should note that the terms of the Contract will be updated in line with any newly updated and published version of the NHS Standard Contract prior to contract award. NHS England may vary the terms of the Contract annually in line with updates to the relevant NHS Standard Contract for the relevant year.

6.2.5 IMPORTANT -the core Contract terms and conditions are non-negotiable. Bidders may seek clarification only in respect of any points of ambiguity or apparent error in the Contract terms and conditions.

6.2.6 Where the Supplier intends to subcontract clinical services then the Authority requires the Supplier to enter into a sub-contract with such sub-contractors on the basis of the NHS Standard Contract sub-contract, published at:

<https://www.england.nhs.uk/nhs-standard-contract/17-18/>

(updated from time to time and in line with the version of the NHS Standard Contract which is entered into with the Supplier). In accordance with General Condition 12.1 of the Contract, the Authority's approval of such sub-contracting arrangements will be subject to the Authority's approval of the form of sub-contract for such sub-contracted clinical services.

6.2.7 For the avoidance of doubt, the Authority will not mandate terms and conditions for sub-contracts for the supply of goods or non-clinical services. However, unless otherwise agreed with the Authority in writing, the terms and conditions for such sub-contracts shall be subject to the approval of the Authority as it sees fit, in line with General Condition 12.1 of the Contract.

### **6.3 Participating Organisations**

6.3.1 Contracts awarded pursuant to this procurement are for use by the Department of Health and Social Care, Public Health England, the NHS in England, and by private sector organisations working on behalf of the aforementioned.

### **6.4 Contract Duration**

6.4.1 As a result of this procurement the Contract will be entered into with the successful Bidder for an initial period of three (3) years with an option to extend the contract by mutual agreement for a period or periods up to the lesser of the patent expiry or seven (7) years i.e. a maximum total contract length of ten (10) years.

6.4.2 Following expiry or termination of the Contract, the Authority may, or may not, implement new supply arrangements informed by the outcome of this project. Any new arrangements will need to comply with the legislative requirements then in place.

### **6.5 Contract Award and Signature**

6.5.1 Within one month of the Authority notifying the Supplier of the Authority's decision to proceed to award of contract, the Supplier must:

- a) enter into the Contract with the Authority;
- b) enter into all necessary contractual arrangements to put in place the sub-contracting arrangements and/or consortium arrangements which formed part of the Bidder's selection stage / Final Tender submission, including forming any legal entity and provide evidence of this to the satisfaction of the Authority.

6.5.2 The Authority may abandon the procurement if the Bidder does not meet the requirements of paragraph 6.5.1 or where the Authority enters into the Contract with the Supplier but terminates this Contract due to failure by the Supplier to meet the mobilisation requirements and /or conditions precedent set out in the Contract.

6.5.3 No offer or bid is deemed accepted until the relevant contractual documents have been duly signed on behalf of the Authority, the Supplier and all other relevant parties and declared unconditional. No dialogue or communication with the Authority whether prior to, during or subsequent to the submission of any bid implies acceptance of any offer or constitutes an indication that the Bidder will be awarded

the contract. Only the express terms of any written contract(s) which is finally agreed and signed for and on behalf of the relevant parties and which is duly declared unconditional shall have any contractual effect.

## **6.6 Mobilisation**

6.6.1 Mobilisation will commence, subject to agreement, following execution of the Contract and will end at contract commencement. The Supplier(s) may commence mobilisation prior to the contract execution date but this will be at their risk and cost.

## **6.7 Contract Commencement**

6.7.1 The Authority anticipates that contract commencement will be circa 1 April 2022 or such other date as agreed between the Authority and the Supplier.

## **6.8 Conditions of Offer**

6.8.1 A response to an Invitation to submit Final Tender is an irrevocable offer by the Bidder and the Bidder separately undertakes with the Authority that the Final Tender submission will remain open for acceptance by the Authority for up to 21 months from the ISFT submission deadline.

6.8.2 In submitting its ISFT submission, the Bidder warrants, represents and undertakes to the Authority that:

- a) All information and representations made to the Authority by the Bidder, its staff or agents in connection with or arising out of the selection questionnaire (SQ), ITPD, ISFT and/or associated documents, are true, complete and accurate;
- b) It has made its own investigations and undertaken its own research and due diligence and has satisfied itself in respect of all matters (whether actual or contingent) relating to the SQ, ITPD, ISFT and associated documents and that it has not submitted its Bid Submission in reliance upon any information, representation or assumption which may have been made by or on behalf of the Authority (save in respect of any information which is expressly warranted by the Authority); and
- c) Where there is a change to the information provided to the Authority at any time the Bidder must advise the Authority as soon as practicable, even if this is prior to the date of submitting the Tender / Final Tender submission and disclose such changes in full.

6.8.3 The Authority reserves the right to retain all and any of the information supplied to it by the Bidder(s).

## **6.9 Transition from Current Arrangements**

6.9.1 In the event that a contract is awarded as a result of this procurement, then that contract will take precedence over any existing contracts or framework agreements for the supply of the antimicrobial to the NHS in England.

## **6.10 Contract Monitoring and Management**

6.10.1 Monitoring & Reporting:

### **Supplier Monthly Reporting**

a) The Supplier shall provide to the Authority by the 10<sup>th</sup> working day of each month, a report setting out, as a minimum, the quantity of antimicrobial delivered to each Purchasing Authority and the delivery date together with any other information reasonably requested by the Authority.

### **Supplier Quarterly Reporting**

b) The Supplier will provide a quarterly report by the 15<sup>th</sup> working day of the month after the quarter, detailing its performance, together with supporting evidence, against each of the performance criteria.

### **Authority Monthly Reporting**

c) The Authority shall provide to the Supplier by the 10<sup>th</sup> working day of each month, a report setting out the quantity of antimicrobial dispensed in secondary care (e.g. via Blueteq data) and primary care (via NHS BSA data);

6.10.2 Contract Management

- a) The Authority anticipates undertaking contract review meetings with Suppliers at least quarterly, with monthly meetings during the initial six (6) month period of the Contract.
- b) The contract management arrangements will be discussed during dialogue; however, the quarterly review meetings will include validating the Suppliers performance against the performance criteria in the previous quarter.

## 7. Governance & Administration

### 7.1 Definitions

7.1.1 For the purposes of this ITPD the capitalised words and expressions that follow have the meanings hereby assigned to them unless the context specifically requires otherwise.

<b>Agreement</b>	the agreement to be entered into between the Authority and the winning Bidder in respect of the Requirement
<b>Authorised Representative</b>	the nominated person authorised on behalf of the Bidder
<b>Authority and / or Contracting Authority</b>	the NHS Commissioning Board, referred to as “ <i>NHS England</i> ”
<b>Bidder</b>	the person, firm, company or consortium that has been invited to respond to this ITPD
<b>Competitive Dialogue</b>	a procedure, pursuant to the Public Contracts Regulations 2015 as amended (the “Regulations”) by which the Authority will, with the aim of meeting its Requirements, conduct the procurement of the Requirement
<b>Contract or Draft Contract</b>	the draft terms and conditions of contract and associated schedules set out in <a href="#">Annex 8</a> (Draft Contract) to this ITPD
<b>Deliverables</b>	the deliverables set out in 3.5.3 of this ITPD which Bidders are required to respond to in their Initial Solution
<b>Existing Antimicrobial</b>	an antimicrobial with an EU license and a UK launch dated on or between 1 January 2017 and 31 December 2018 and the Licensed Indication(s) include one or more pathogens on the WHO priority pathogen list against which the antimicrobial is active
<b>Final Tender</b>	the “best and final offer” to be submitted by Bidders in their final tender submission
<b>Invitation to Participate in Dialogue or ITPD</b>	this invitation to participate in dialogue, which is a part of the Competitive Dialogue process for the procuring the Requirement
<b>Invitation to Submit Final Tender or ISFT</b>	the final tender document to be issued in this process, which will invite Bidders to submit their Final Tenders
<b>Initial Solution</b>	a Bidder's initial proposals for meeting the Authority's Requirements in accordance with the terms of this ITPD

<b>Material Sub-Contractor</b>	any sub - contractor, whether of the Supplier itself or at any further level of sub - contracting, under any Sub – Contract where the subcontractor is providing clinical services or where the value of the Sub – Contract is valued at more than 10% of the total value sub-contracted by the Supplier
<b>New Antimicrobial</b>	an antimicrobial that is timetabled to be licensed for use and launched in the UK prior to the 1st January 2021 and the Licensed Indication(s) include one or more pathogen on the WHO priority pathogen list against which the antimicrobial is active
<b>Procurement</b>	this procurement process relating to the supply and delivery of antimicrobials
<b>Procurement Documents”</b>	the documents referred to in this ITPD and all associated Appendices, Annexes or other documents referred to therein
<b>Relevant Organisation</b>	any organisation(s) or person that the Bidder is relying on when making their ITPD submission and/or for the purpose of the performance of any obligation on the part of the Supplier under any ensuing Agreement, including without limitation: the Bidder; the Supplier; each Material Sub-Contractor
<b>Regulations</b>	the Public Contracts Regulations 2015 (as amended)
<b>Requirement</b>	the antimicrobial medicine which the Authority wishes to procure, information and details of which are set out in <a href="#">Annex 1</a> of this ITPD document and “Requirements” shall be construed accordingly
<b>Rules of Engagement</b>	the Authority’s rules of engagement concerning the conduct of the dialogue phase of this procurement
<b>Sub – Contract</b>	any sub - contract entered into by the Supplier or by any Sub - Contractor of any level for the purpose of the performance of any obligation on the part of the Supplier under this Contract
<b>Sub – Contractor</b>	any sub - contractor, whether of the Supplier itself or at any further level of sub - contracting, under any Sub – Contract
<b>Supplier(s)</b>	he Bidder who has entered into a Contract with the Authority to supply and delivery antimicrobials
<b>Tender</b>	the responses (including Initial Solution) submitted by Bidders in accordance with the terms of this ITPD and ISFT issued by the Authority during the course of this Competitive Dialogue process

<b>TUPE</b>	Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246)
<b>Update</b>	a written notification by the Authority to the Bidders. Updates may be issued during the tender period to amend or to provide further clarification to any part of the ITPD

## 7.2 General

7.2.1 By signing/submitting a Tender, the Bidder and each Relevant Organisations warrants that, save as disclosed in writing to the Authority with the Tender, any information supplied by it remains true and that it has:

- a) Not passed a resolution, nor is it the subject of an order by the court, for the company's winding-up otherwise than for the purposes of bona fide reconstruction or amalgamation, nor has it had a receiver, manager or administrator on behalf of a creditor appointed in respect of its business or any part thereof, nor is it the subject of proceedings for any of the above procedures, nor is it the subject of similar procedures under the law of any other states;
- b) Not been convicted of a criminal offence relating to the conduct of its business or profession;
- c) Not been convicted of any of the offences listed in Regulation 57 "Mandatory exclusions" of the Public Contracts Regulations 2015;
- d) Not been in in any of situations listed in Regulation 57 "Mandatory and discretionary exclusions for non-payment of taxes etc" or "Discretionary exclusions" of the Public Contracts Regulations 2015, subject to the exercise of Discretion, or acceptance of evidence of Self-Cleaning, on behalf of the Authority, as provided for under Regulation 57.
- e) Not made any material misrepresentation in providing any of the information required in relation to the or ITPD or ISFT; and
- f) Not disclosed, copied, reproduced or distributed and will not disclose, copy, reproduce or distribute any information contained in the Procurement Documents or supplied by the Authority to any third party at any time except for the purpose of enabling a response to the ITPD or ISFT to be prepared.

7.2.2 The Authority may in its own absolute discretion extend the closing date and time for receipt of ITPD and/or ISFT responses. Any extension granted will apply to all Bidders.

### **7.3 Guidance and Compliance**

7.3.1 Bidders should read these instructions carefully before submitting a response to this ITPD. Failure to comply with these requirements for completion and submission of the Tender response may result in the rejection of the Tender response. Bidders are therefore advised to acquaint themselves fully with the instructions and conditions set out in this ITPD.

7.3.2 All Tenders received by the Authority will be checked for compliance with the submission requirements set out in this ITPD. If a Tender is not considered compliant, the Authority will not be obliged to carry out any further evaluation and the Bidder may be eliminated from the procurement. During this period, clarification on any aspect of the Tender may be sought.

7.3.3 A compliant Tender is defined as one that meets the following criteria (as defined in this ITPD) (i) it is delivered before the Tender submission deadline and (ii) it meets the Tender response requirements;

7.3.4 The Authority requires adherence to all instructions and conditions within this ITPD from each of the Bidders and the participation in the tender process by each Bidder shall be construed as unqualified acceptance of such obligations by and on behalf of that Bidder.

### **7.4 Enquiries**

7.4.1 Any enquiries must be submitted in writing via the Atamis e-tendering portal.

7.4.2 Except where the response to an enquiry relates to commercially confidential matters, the Authority's will copy their responses to all Bidders in accordance with paragraph 6 below in the form of a clarification via the Atamis e-tendering portal.

### **7.5 Tender Validity**

7.5.1 All Tenders submitted by Bidders must remain open for acceptance up to 21 months from the ISFT submission deadline. Offer Prices must be firm (i.e. not subject to variation) for the period of the contract subject only to any variation provisions contained in the contract documents.

### **7.6 Language**

7.6.1 All documentation and communication shall be in English.

## **7.7 Tender Preparation Costs**

7.7.1 Each Bidder shall be solely responsible for all the costs it incurs in the preparation and submission of its Tender up to and including the award of any contract by the Authority. This shall also be deemed to cover the cost of attending any pre or post Tender meetings and dialogue and, should a Bidder be successful, the preparation of contract documents. The Authority shall in no event be responsible or liable for any such costs regardless of the conduct or outcome of the bidding process, and in this respect, the Bidder shall have no recourse to the Authority.

## **7.8 Variant Bids**

7.8.1 Variant bids are NOT permitted.

## **7.9 ITPD Updates**

7.9.1 Throughout the Competitive Dialogue process, the Authority may issue Updates, which will be identified by a number and the date. These will be issued via the Atamis e-tendering portal.

7.9.2 Such Updates will contain details of any amendments, additions or variation to the information contained in this ITPD document or documents previously provided, together with any further information, which may assist the Bidders in the preparation of their submissions. No statements issued by the Authority in relation to this or any other documents shall be relied upon unless ratified by an Update.

## **7.10 Bidder's Authorised Representative**

7.10.1 All communication relating to this Procurement will be sent via the NHS England Atamis E-Tendering Portal for the attention of the Bidder's Authorised Representative. The Authorised Representative must have full authority to represent the Bidder and attend any meetings on the Bidder's behalf. The Authority may, at any time, request documentary proof of such authority. Bidders shall notify the Authority of any changes to the Authorised Representative's contact details as soon as practicable.

## **7.11 Confidential Information**

7.11.1 Confidential information means all information which is supplied by the Authority to a Bidder whether in writing, orally or in any other form, directly or indirectly from or pursuant to discussions with such Bidder or which is obtained through observations made by such Bidder which is designated by the Authority as confidential or which is otherwise of a confidential nature. Each Bidder shall hold in confidence any confidential information, provided that such Bidder shall not be restricted from passing such information to its professional advisers, or its proposed sub-contractors

(subject to obtaining appropriate confidentiality undertakings) but only to the extent necessary to enable it to prepare its Tender and participate in this procurement.

- 7.11.2 The Authority may disclose detailed information relating to Bidders' Tender responses to the Authority's officers, employees, agents or advisers and they may make Bidders' Tender responses available for private inspection by the Authority's officers, employees, agents or advisers.
- 7.11.3 The Authority also reserve the right to disseminate information that is materially relevant to all Bidders, even if the information has only been requested by one Bidder, subject to the duty to protect any Bidder's commercial confidence in its responses.
- 7.11.4 Should Bidders wish to avoid such disclosure (for example, on the basis that the request or response contains commercially confidential information or may give another Bidder a commercial advantage) the request must be clearly marked "In Confidence - not to be circulated to other Bidders" and the Bidder must set out the reason(s) for the request for non-disclosure to other Bidders.
- 7.11.5 If the Authority considers that, in the interests of open and fair competition, it is unable to respond to the question or request for clarification or further information on a confidential basis, it will inform the Bidder who has submitted it. The Bidder must as soon as practicable thereafter respond in writing requesting that either the query be withdrawn or treated as not confidential. The Authority will deem that the question or request for clarification or further information has been withdrawn if the Authority is not contacted in writing via the Atamis e-tendering portal within 2 working days following the Bidder being so informed.
- 7.11.6 The Authority will act reasonably as regards the protection of commercially sensitive information relating to the Bidder, subject always to the Authority's duties under the Freedom of Information Act 2000 (see paragraph 15 below).

## **7.12 Staff Transfers - Transfer of Undertakings Protection of Employment (TUPE)**

- 7.12.1 The Authority believes that Transfer of Undertakings (Protection of Employment) Regulations 2006 (TUPE) will not apply to transfer the employment of any individuals from the Authority or any third-party supplier of the Authority to the successful Bidder at the commencement of the Contract.
- 7.12.2 Bidders are required to take their own advice on whether TUPE will apply to the tender and their specific bid. For the avoidance of doubt, the Authority have a

facilitating role only and are not in a position to make any statement regarding any potential obligations the tender may give rise to under TUPE.

- 7.12.3 The Authority makes no warranty that the information provided, or the beliefs expressed are correct and accepts no liability and provides no indemnity for any errors or omissions or inaccuracies in the information provided or the beliefs expressed.
- 7.12.4 The successful Bidder will be required to indemnify the Authority against all possible claims under TUPE. It is a further requirement that the successful Bidder will pass on all details of their own workforce towards the end of the Contract period so that this information can be passed to other bona fide Bidders to enable them to assess their obligations under TUPE in the event of a subsequent transfer occasioned by a future tender process. These terms will be detailed in the Contract entered into by the successful Bidder.

### **7.13 No Inducement or Incentive**

- 7.13.1 The Procurement Documents are issued on the basis that nothing contained in them shall constitute an inducement or incentive nor shall have in any other way persuaded a Bidder or Relevant Organisation to submit a Bid or enter into any contractual agreement.

### **7.14 Freedom of Information**

- 7.14.1 Bidders are reminded that the Authority is subject to the requirements of the Freedom of Information Act 2000 ("FoIA") and the Environmental Information Regulations 2004 ("EIR"). Accordingly, the Authority may be required to disclose, on request, information submitted to it by Bidders in connection with the ITPD or ISFT. Information may be exempt from disclosure under FoIA where its disclosure would breach confidentiality or be likely to prejudice the commercial interests of any person, but the Authority can give no assurances as to whether or not information received from Bidders in connection with the ITPD or ISFT would be disclosed in response to a request made under FoIA. In the event that such a request is received by the Authority, the Authority shall, in accordance with its obligations under the Code of Practice made under section 45 FOIA, consult with any party whose interests are likely to be affected by disclosure and take their views into account. However, the Authority shall be responsible for determining at its absolute discretion whether any such information is exempt from disclosure in accordance with the provisions of the FoIA or the EIR and whether any such information is to be disclosed in response to an information request. Even if the Authority initially refuses to disclose requested

information, Bidders should be aware that disclosure may be enforced by the Information Commissioner or the Courts.

## **7.15 Copyright**

7.15.1 Bidders are reminded that the copyright to this ITPD rests with the Authority and its appointed advisors. This ITPD may not either in whole or in part be copied, reproduced, distributed or otherwise made available to any other third party without the prior written consent of the Authority except in relation to the preparation of a Tender. All documentation supplied by the Authority in relation to this ITPD is, and shall remain the property of the Authority and must be returned on demand, without any copies being retained.

## **7.16 Canvassing**

7.16.1 Any Bidder who directly or indirectly canvasses any member of the Authority or any of its officials or representatives concerning the contract award process for Requirement may be disqualified.

## **7.17 Collusive Submissions**

7.17.1 Any Bidder who:

- a) Fixes or adjusts the Tender rates and prices quoted by it under or in accordance with any agreement or arrangement with any other person; or
- b) Communicates to any person other than the Authority the amount or approximate amount of its proposed Tender (except where such disclosure is made in confidence in order to obtain quotations necessary for the preparation of the Tender for insurance or similar activity); or
- c) Offers or agrees to pay or give, or does pay or give any sum of money inducement or valuable consideration directly or indirectly to any person for doing or having done or causing or having caused to be done in relation to this or any other Tender or proposed Tender, any act or omission; will be (without prejudice to any other civil remedies available to the Authority and without prejudice to any criminal liability which such conduct by a Bidder may attract) disqualified. The Bidder warrants that its Tender shall be bona fide and shall be intended to be competitive and that it has not done and will not do at any time any of the acts set out in paragraph 11.1 above.

## **7.18 Bidder Membership and Eligibility**

- 7.18.1 The Authority must be notified in writing of any change in the control, composition or membership of a Bidder that has taken place subsequent to the Bidder's selection to participate in the Competitive Dialogue and of any other material change to the Bidder's response to the SQ, particularly any material change in the financial position of a Bidder. The Authority reserves the absolute right to withhold approval to any such changes and to disqualify the Bidder concerned from any further participation in the procurement process.
- 7.18.2 Bidders are reminded of the eligibility requirements that apply to the procurement process at all times. In particular, these include the provisions set out in Regulation 57 of the Public Contracts Regulations 2016. Any change in the eligibility of a Bidder must be notified immediately to the Authority in writing and may result in such Bidder being disqualified from any further participation in the procurement process.

## **7.19 Consortia and Subcontracts**

- 7.19.1 For expressions of interest, Tenders and Final Tenders, the Authority has drawn a distinction between prime and subcontracting arrangements and consortium arrangements. The Authority recognises these terms are often used interchangeably by some Bidders and wishes Bidders to apply the following common terminology to company groupings in the future.
- 7.19.2 Where groups of companies come together specifically for the purpose of bidding for appointment as the winning service provider and envisage they will establish a special purpose vehicle as the prime contracting party with the Authority, the Authority will characterise these arrangements as consortium arrangements.
- 7.19.3 Where groups of companies come together specifically for the purpose of bidding for appointment as the service provider but envisage that one of their number will be the service provider, the remaining members of that group will be subcontractors to the service provider.
- 7.19.4 The Authority requires all Bidders (if they have not done so already) to identify which of these two arrangements apply in the case of their proposal and precisely which entity they propose to be the service provider.
- 7.19.5 The Authority also recognises that Bidders may wish to extend or modify their groupings of subcontractors or consortium members to meet the existing and future requirements of the Authority. To ensure all Bidders are treated in a transparent and non-discriminatory manner, the Authority would like to give the guidance set out below.

7.19.6 Bidders should note that the principles set out below are provided only for guidance and do not constitute a definitive or exhaustive view of the approach the Authority will take in any individual circumstances. Bidders should notify the Authority of any proposed changes to the identity of consortia or subcontractors.

7.19.7 The guidance is as follows:

- a) where an organisation has identified itself as a Bidder, the withdrawal of that organisation in favour of another member of that organisation's group of subcontractors or otherwise will be treated as the withdrawal of the Bidder itself and will result in the disqualification of the Bidder (and so its subcontractors);
- b) where an organisation has identified itself as a Bidder, it is at liberty, until the submission of its Tender, to revise the identity of its subcontractor grouping, provided this does not cause the Authority to reconsider the basis on which the Bidder qualified and was selected;
- c) where two or more Bidders wish to consolidate their bids into one bid, specific guidance from the Authority should be sought;
- d) if a Tender is submitted by a consortium, the Authority will require any agreement(s) to be entered into by all consortium members on a joint and several basis, or by a lead single entity on behalf of the consortium. In the latter case, other consortium members may be required to enter into direct agreements with or guarantees to the Authority in connection with their sub-contracts and the Authority will require a right of approval over sub-contracts. In the case of a lead entity which is specially created for this contract, the Authority will also require confirmation that the consortium will provide a sufficient level of security, whether by way of guarantees from consortium members or their parents, or otherwise.
- e) where a group of organisations has identified itself as a consortium, the grouping may change (by addition or removal of consortium members), provided this does not change the fundamental character of the consortium or cause the Authority to reconsider the basis on which that consortium qualified and was selected;
- f) generally, the Authority will be more concerned with the loss of subcontractors or consortium members than with the addition of subcontractors or consortia members;

- g) once this ITPD has been issued and the Final Tender received, Bidders will be at liberty to continue to finalise their consortium or subcontracting arrangements until the contract award, unless changes to the constitution of those consortia or subcontracting arrangements would cause the Authority to reconsider the basis on which the Bidder was allowed to continue in the procurement process; and
- h) once a contract has been awarded to a Bidder, the Authority would not expect any changes in this group of subcontractors to occur without its consent and the final form Contract will contain appropriate provisions.

## **7.20 Authority's Advisors**

7.20.1 Bidders should note that the advisers currently appointed on behalf of the Authority in relation to this procurement are:

Legal - Blake Morgan LLP

7.20.2 The Authority may, at their sole discretion, appoint additional advisors.

7.20.3 Each Bidder acknowledges that by virtue of submitting a Tender in response to the ITPD it waives any right of objection which it has or may have in relation to the Authority's appointment of professional advisers. The Authority reserves the right to disqualify any Bidder which refuses to provide such a waiver.

## **7.21 Publicity**

7.21.1 No publicity regarding the procurement of the Requirement or the award of any contract will be permitted unless and until the Authority has given express written consent to the relevant communication.

## **7.22 Conflict of Interest**

7.22.1 Bidders are instructed to ensure that their potential appointment as the service provider to the Authority for the provision of the Requirement has not and will not create any conflict of interest or any situation that might compromise or prejudice the Authority's duty to manage an open, fair, non-discriminatory and competitive procurement process. In the event of a conflict (or potential conflict) arising at any time during the procurement process, the affected Bidder must report the occurrence of an actual or potential conflict and the means for resolving it to the Authority as soon as reasonably practicable.

7.22.2 Failure to declare any actual or potential conflict and/or failure to address such conflict to the reasonable satisfaction of the Authority may result in a Bidder being disqualified from this procurement.

### **7.23 Right to Reject Bidder Responses**

7.23.1 The Authority reserves the right to reject or disqualify a Bidder where:

- a) A Tender response is submitted late, is completed incorrectly, is materially incomplete or fails to meet the Authority's Requirements which have been notified to Bidders;
- b) the Bidder and/or a member(s) of its supply chain are unable to satisfy the terms of Regulation 57 of the Public Contracts Regulations 2015 (as amended) at any stage during the tender process;
- c) the Bidder and/or a member(s) of its supply chain are guilty of material misrepresentation in relation to information provided by the Bidder during the selection stage and/or in connection with any Tender response;
- d) the Bidder and/or a member(s) of its supply chain contravene any of the terms and conditions of this ITPD or other document issued by the Authority or
- e) there is a change in identity, control, financial standing or other factor impacting on the selection and/or evaluation process affecting the Bidder and/or a member(s) of its supply chain.

### **7.24 The Authority's Rights**

7.24.1 Although it is intended that the remainder of this procurement will take place in accordance with this ITPD the Authority reserves the right to:

- a) waive the requirements of this ITPD;
- b) disqualify any Bidder that does not submit a compliant Tender response in accordance with the instructions in this ITPD;
- c) annul the Tender process in its entirety;
- d) withdraw this ITPD at any time, or to re-invite Tender responses on the same or any alternative basis;

- e) choose not to award any contract as a result of the current procurement process; and
- f) make whatever changes it sees fit to the timetable, structure or content of the procurement process and this ITPD from time to time without prior (or any) notice being given by the Authority.

## **7.25 Interpretation**

7.25.1 In the Procurement Documents, except where the context otherwise requires:

- a) Words importing one gender include all other genders and words importing the singular include the plural and vice versa.
- b) Enactment means any statute or statutory provision (whether of the United Kingdom or elsewhere), subordinate legislation (as defined by s.21 (1) Interpretation Act 1978) and any other subordinate legislation made under any such statute or statutory provision.
- c) A reference to any enactment shall be construed as including a reference to:
  - 1. any enactment which that enactment has directly or indirectly replaced (whether with or without modification); and
  - 2. that enactment as re-enacted, replaced or modified from time to time, whether before, on or after the date of the Procurement Documents.
- d) the Definitions (7.1), any abbreviations, the headings to the sections of the Procurement Documents and the Annexes thereto are for ease of reference only and shall not affect the construction of the Procurement Documents;
- e) any Appendices or Annexes to the Procurement Documents form part of the Procurement Documents and will have the same force and effect as if expressly set out in the body of the Procurement Documents;
- f) in the event of any inconsistency between the provisions of the Procurement Documents and any previously issued documents, the provisions of the Procurement Documents shall prevail

## **7.26 Governing Law**

7.26.1 The laws of England and Wales and the exclusive jurisdiction of the Courts of England and Wales; shall apply to this Procurement, ITPD, ISFT, the Competitive

Dialogue, the Requirement and, subject to applicable law, any dispute, including any non-contractual dispute arising therefrom.

## **8. Annexures**

**Annex 1:** Authority Requirements

**Annex 2:** Dialogue Meeting Schedule

**Annex 3:** Award Questions and Criteria

**Annex 4:** Clinical Questions Response Template

**Annex 5:** Non-clinical Questions Response Template

**Annex 6:** Finance Response Template

**Annex 7:** Health Technology Assessment Process

**Annex 8:** Draft Contract

**Annex 9:** Confidentiality Undertaking

**Annex 10:** Freedom of Information Declaration

**Annex 11:** Issues Log